Kaiser Foundation Health Plan of Colorado

Utilization Management Clinical Review Criteria

Utilization Management Department
KPCO Criteria for Air Ambulance Reviews

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Air Ambulance Reviews

This guideline was developed to support clinician and utilization review teams regarding appropriate clinical criteria for Air Ambulance Reviews. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Air Ambulance Reviews

Retrospective Approval for Air Ambulance transportation may be considered if ALL of the following are met:

1. Transportation by air is only covered for transportation to a hospital, and
    a. Transportation to non-hospital facilities is not covered (MMCM Ch.15 sec. 20.3 and incorporated to Commercial rules by reference).
2. The time saved by air transportation has a **material effect** on the patient's medical care, and
    a. For example, the patient would have come to material harm had they not been transported by air.
3. The air transport provider **did not avoid transport to a closer facility suitable** to treat the patient's urgent need **unless** there is documentation that the nearest suitable facility did not have an appropriate bed available.
    a. For example, if the patient is being transported for stroke care the air transport provider did not pass a qualified stroke center.
    b. Passing a facility qualified to manage the emergency care need is *prima fasciae* evidence of a profit motive for the transport, rather than a primarily medical one. If the patient's condition is so emergent to require air transportation a provider cannot in good conscience pass a suitable facility and unnecessarily prolong transport time absent a compelling medical reason for doing so, which must be documented in the record.
    c. This section is waived if the facility that was passed was on diversion status, refused transfer, or was otherwise unable to accommodate the patient's need at the time of transfer.
    d. If criteria for Air Ambulance Transport is otherwise met, the claim may pay at the rate for transport between the sending facility and the closest appropriate facility capable of accepting the patient.

If criteria 1 and 2 above are not met for Air Ambulance transportation and ambulance transport is indicated then the claim may pay at the rate payable for ground ambulance.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, including use of MMCM Ch. 15 sec 20.3 and 10.4.1 - Coverage Requirements (Rev. 1, 10-01-03) A3-3114.C.11.A, B3-2120.4A [requirements 2,3, and 4].	01.2022
1.1	Payment clause at end was added, as well as 4.d. Medicare Benefit Policy Manual Ch.10 was reviewed and adjustments made for consistency. MBPM is incorporated for Commercial reviews by reference.	03.2022
1.2	Slight change in wording on (1). Combined the (2) and (3) – only 1-3 now (no longer [4]). De-lettered (d) and made it the second to last statement since it didn't fit with the flow of the lettered bullet points. Review done by Dr. Swan Davis, D.O., UMMD	9.2023
1.3	Deleted the 30 minute time saving requirement in (2)	5.2024
1.4	Reworded the bolded words in 3. Moved the statement that is now 3.d. into that section rather than a separate sentence after section 3. Reworded the last sentence in the GL to state "if criteria 1 and 2 above."	8.2024
1.5	Routine annual review – no changes made	9.2024

Utilization Management Department
KPCO Criteria for Applied Behavior Analysis (ABA)

Sub department(s): Utilization Management Behavioral Health	Last Review: 04.2024 Next Review: 04.2025 Approved By: KPCO UM Committee

Title:
KPCO Criteria for Applied Behavior Analysis (ABA)

This guideline was developed to support clinician and utilization review teams about appropriate use of ABA services. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions outlined by this guideline.

Criteria for ABA Evaluation

Essential Elements: All of the following criteria must be met:

1. The member has a diagnosis for which there is evidence that ABA may be an effective and appropriate therapeutic intervention (i.e., autism spectrum disorder) obtained by a qualified healthcare professional (i.e., licensed psychologist/psychiatrist, developmental pediatrician) who is experienced in the diagnosis and treatment of the condition. It is deemed that ABA is the most appropriate therapeutic intervention to treat the member's symptoms.
2. The member cannot adequately participate in home, school, or community activities, and/or the member presents a safety risk to self or others. The member's risk of imminent danger to self or others is at a level where the member can appropriately engage in ABA services and the member is able to adequately participate in the services being provided. Psychiatric and comorbid biomedical/developmental conditions have been evaluated and are deemed appropriate to engage in ABA services.
3. The care being requested is not custodial, educational, or vocational in nature. Custodial care is defined as any type of care where the primary purpose is to attend to the member's daily living activities which do not entail or require the continuing attention of trained medical or paramedical personnel (such as maintaining hygiene, safety, and independent living). The services will not be rendered by a parent, legal guardian, or legally responsible person.

Criteria for Initial ABA Treatment (first 6 months)

All of the following criteria must be met:

1. All essential elements are met.
2. There is demonstration of functional impairment on an approved standardized scale of functioning (current version of Vineland or ABAS are acceptable). The impairment must be at least one standard deviation below the mean OR represent a significant risk of harm to self or others.
3. There is commitment to active participation in treatment by parents/guardians, caregivers, and other people impacted by and in position to affect patient behavior.
4. A comprehensive clinical evaluation was completed by a Board Certified Behavior Analyst (BCBA or BCBA-D) supporting medical necessity of time-limited ABA services which includes ALL of the following:
    a. Vineland-3, or ABAS-3 assessment completed within 30 days of plan submission.
    b. Individualized and measurable treatment goals for acquisition, reduction, and maintenance behaviors including objective baseline measures and quantifiable criteria for progress.

c. Behavior Intervention Plan and Crisis Plan (if necessary).
d. Documentation of ongoing collaboration and coordination of care with all outside service professionals (i.e., school, KP, SLP, OT, PT).
e. Individualized goals for parent/caregiver training including objective baseline measures and qualifiable criteria for progress.
f. Measurable and individualized discharge and fade plan.

5. Completion of a Prior Authorization Request (PAR) form in full, including requested timeframe of service not to exceed 6 months. Utilization Management has the right to reduce the timeframe between reviews to less than 6 months due to (but not limited to) any of the following reasons: acuity of the member's presentation, request for increased hours, lack of parent participation, significant progress being made, member is close to meeting discharge criteria.
6. The level of impairment justifies the number of treatment hours being requested. If more hours are being requested than the prior authorization, or additional hours are being requested to ADD to the current authorization, significant clinical justification is required. If the member is making sufficient progress at the current dosage, additional hours may not be authorized. The Assessment of Symptom Severity (Appendix A-B) and the CPT Code Criteria (Appendix C) are used to determine treatment dosage.

Criteria for Continued ABA Treatment

All of the following criteria must be met:

1. All essential elements are met.
2. Reevaluation of progress and response to intervention has been performed to assess the need for continued ABA. There has been a repeat administration of a standardized scale of functioning (current version of Vineland or ABAS are acceptable). The current level of impairment is at least one standard deviation below the mean OR represents a significant risk of harm to self or others.
3. The frequency of target behaviors has improved since the last review. If improvement is not seen, there has been modification of the treatment, additional assessments have been conducted, barriers have been addressed and/or there have been appropriate consultations from other staff or experts.
4. There is documented active participation in treatment by parents/guardians, caregivers, and other people impacted by and in position to affect patient behavior.
5. A comprehensive and updated clinical evaluation was completed by a Board Certified Behavior Analyst (BCBA or BCBA-D) supporting medical necessity of time-limited ABA services which includes ALL of the following:
    a. Repeat Vineland-3 or ABAS-3 assessment completed within 30 days of plan submission.
    b. Individualized and measurable treatment goals for acquisition, reduction, and maintenance behaviors including objective baseline measures, quantifiable criteria for progress, current level of improvement, any barriers to treatment, and any treatment modifications.
    c. Behavior Intervention Plan, Functional Behavior Assessment, and Crisis Plan (if necessary).
    d. Documentation of ongoing collaboration and coordination of care with all outside service professionals (i.e., school, KP SLP, OT, PT). If coordination of care was not achieved due to lack of response from providers/resources, there is documentation of at least 3 attempts to coordinate.
    e. Individualized goals for parent/caregiver training including objective baseline measures, qualifiable criteria for progress, current level of improvement, any barriers to treatment, and any treatment modifications.
    f. Measurable and individualized discharge and fade plan with current progress and any barriers. The treatment plan documents a gradual tapering of higher intensities of intervention and a shifting to supports from other sources (i.e., school, parents/guardians) as progress continues.
6. Completion of a Prior Authorization Request (PAR) form in full, including requested timeframe of service not to exceed 6 months. Utilization Management has the right to reduce the timeframe between reviews to less than 6 months due to (but not limited to) any of the following reasons: acuity of the member's presentation, request for increased hours, lack of parent participation, significant progress being made, member is close to meeting discharge criteria.

7. The level of impairment justifies the number of treatment hours being requested. If more hours are being requested than the prior authorization, or additional hours are being requested to ADD to the current authorization, significant clinical justification is required. If the member is making sufficient progress at the current dosage, additional hours may not be authorized. The Assessment of Symptom Severity (Appendix A-B) and the CPT Code Criteria (Appendix C) are used to determine treatment dosage.

Criteria for Discharge from ABA Treatment

At least ONE of the following criteria are met:

1. The essential elements are no longer met.
2. There has been improvement of two or more standard deviations across multiple domains OR the member is within one standard deviation of the mean on an approved standardized assessment.
3. There has been improvement of one or more standard deviation in all domains for successive authorization periods.
4. There is adequate stabilization of all challenging behaviors.
5. There are no meaningful, measurable, functional improvement changes, or progress has plateaued (the member fails to respond to ABA services) without documentation of significant interfering events (i.e., serious physical illness, major family disruption, change of residence) and after encountering different ABA techniques/modifications across two or more successive authorization periods. There is no reasonable expectation that termination of the current treatment would put the individual at risk for decompensation or the recurrence of signs and symptoms that necessitated treatment.
    a. For progress to be meaningful, it must be:
        i. Confirmed through data (mastery of at least 30% of treatment goals each review period)
        ii. Confirmed through norm-referenced assessment tools (improvement of at least 1 standard deviation)
        iii. Durable over time beyond the end of the actual treatment session
6. Treatment is making symptoms persistently worse.
7. Parents/guardians have not participated in treatment for successive authorization periods.

Appendix A:

Assessment of Symptom Severity – Vineland-3

Assessment of Symptom Severity *This should be used as a guide. Higher/lower hours can be requested with clinical rationale* Put a check in the white box that corresponds to the member's current Vineland-3 Score Maladaptive Behavior Index is *required* if choosing to complete Vineland assessment				
Functional Impairment	**None**	**Mild**	**Moderate**	**Severe**
SD from Mean	**≤ 1 below**	**>1 below**	**>1.5 below**	**>2 below**
Standard Scores	**86 and above**	**79 – 85**	**71 – 78**	**70 and below**
Communication	☐	☐	☐	☐
Daily Living	☐	☐	☐	☐
Socialization	☐	☐	☐	☐
Functional Impairment	**None**	**Mild**	**Moderate**	**Severe**
SD from Mean	**≤ 1 above**	**>1 above**	**>1.5 above**	**>2 above**
V-Scale Scores	**1 – 17**	**18**	**19 – 20**	**21 – 24**
Internalizing Behavior	☐	☐	☐	☐
Externalizing Behavior	☐	☐	☐	☐
Number of Direct Treatment Hours Per Week Use the row that matches the member's current participation in school. *NOTE* if it is summer break, use the row that fits the member's expected school status next school year. If the member is not in school due to completion of high school, use the "full time school" row. For each column, add the corresponding number of hours for each "check" received in the white boxes above.				
☐ Not in School	**0 hours**	**1-2 hours**	**3-4 hours**	**5-6 hours**
☐ Part Time School	**0 hours**	**1-2 hours**	**3-4 hours**	**5 hours**
☐ Full Time School	**0 hours**	**1 hours**	**2 hours**	**3 hours**
TOTAL				

This table supports recommendations for direct treatment hours, codes 97153, 97154, 97158, and 0373T *combined*.

Hours Recommended by Assessment _____ Hours Recommended by the BCBA _____

Does the BCBA's clinical recommendation match the assessment? ☐ Yes ☐ No
If no, provide clinical rationale below.

Clinical Rationale for Hours Request being higher or lower than indicated by this assessment:

Appendix B:

Assessment of Symptom Severity – ABAS-3

Assessment of Symptom Severity *This should be used as a guide. Higher/lower hours can be requested with clinical rationale* Put a check in the white box that corresponds to the member's current ABAS-3 Score				
Functional Impairment	**None**	**Mild**	**Moderate**	**Severe**
SD from Mean	**≤ 1 below**	**>1 below**	**>2 below**	**>3 below**
Standard Scores	**90 and above**	**80-89**	**71-79**	**70 and below**
Conceptual	☐	☐	☐	☐
Social	☐	☐	☐	☐
Practical	☐	☐	☐	☐
Number of Direct Treatment Hours Per Week Use the row that matches the member's current participation in school. *NOTE* if it is summer break, use the row that fits the member's expected school status next school year. If the member is not in school due to completion of high school, use the "full time school" row. For each column, add the corresponding number of hours for each "check" received in the white boxes above.				
☐ **Not in School**	**0 hours**	**1-4 hours**	**5-7 hours**	**8-10 hours**
☐ **Part Time School**	**0 hours**	**1-3 hours**	**4-6 hours**	**7-8 hours**
☐ **Full Time School**	**0 hours**	**1-2 hour**	**2-3 hours**	**4-5 hours**
TOTAL				

This table supports recommendations for direct treatment hours, codes 97153, 97154, 97158, and 0373T *combined*.

Hours Recommended by Assessment _____ Hours Recommended by the BCBA _____

Does the BCBA's clinical recommendation match the assessment? ☐ Yes ☐ No
If no, provide clinical rationale below.

Clinical Rationale for Hours Request being higher or lower than indicated by this assessment:

Appendix C:

CPT Code Criteria

- 97151 – 6 hours (24 units) are sufficient for reassessment and treatment planning. Any requests above this threshold require substantial clinical evidence of medical necessity.
- 97152 – Any requests for use of this code require substantial clinical evidence of medical necessity. Description of the assessment(s) being run by the technician are also required.
- 0362T – Any requests for use of this code require substantial clinical evidence of medical necessity.
- 97153 – The "assessment of symptom severity" must be completed and submitted with each request. If the requested hours differ from those identified by the assessment (either higher or lower), clinical rationale is required. If the member is in school or has other commitments that reduce availability for ABA treatment, the number of hours requested should match what will actually be used. This code can be billed concurrently with code 97155 as long as the descriptors of both codes are met and the rendering providers are different (i.e., QHP & RBT). This code can be billed concurrently with code 97156 or code 97157 as long as the descriptors of both codes are met and the RBT/client are in a separate room from the caregiver/QHP.
- 97154 – Any requests for use of this code must outline what the group targets during these sessions and there must be specific group goals in the plan. This code can be billed concurrently with code 97155 as long as the descriptors of both codes are met and the rendering providers are different (i.e., QHP & RBT). This code can be billed concurrently with code 97156 or code 97157 as long as the descriptors of both codes are met and the RBT/client are in a separate room from the caregiver/QHP.
- 0373T – Any requests for use of this code require substantial clinical evidence of medical necessity.
- 97155 – The industry standard is that up to 2 hours of supervision per 10 hours of direct treatment will be appropriate. Additional requests outside the 2:10 ratio will require substantial clinical evidence of medical necessity. This code can be billed concurrently with code 97153 or 97154 as long as the descriptors of both codes are met and the rendering providers are different (i.e., QHP & RBT).
- 97158 – Any requests for use of this code must outline what the group targets during these sessions and there must be specific group goals in the plan.
- 97156 – Caregiver training should occur at a minimum 1 time per month. If attendance at caregiver training sessions is limited, barriers to treatment and documentation of remediation steps must be submitted. Data is required to be taken during each caregiver training session. This code can be billed concurrently with code 97153 or 97154 as long as the descriptors of both codes are met and the caregiver/QHP are in a separate room from the RBT/client.
- 97157 – Any requests for use of this code must outline what the group goals are. Data is required to be taken during each caregiver training session, individualized to each family. This code can be billed concurrently with code 97153 or 97154 as long as the descriptors of both codes are met and the caregiver/QHP are in a separate room from the RBT/client.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created	10.2022
2.0	The following sections were *removed* from the criteria: Criteria for Admission to Treatment, Coverage for Treatment Planning Hours and Treatment Hours Policy,	3.2024

	Criteria for Continued Care, Criteria for Telehealth Services for ABA, Discharge/Exclusion Criteria, and Alternatives to Procedure. Items removed from the criteria include: specific evaluation measures required within the diagnostic evaluation, age and IQ requirements, assessment of the member's impulse control/emotional and behavioral disturbances/daily living/interpersonal interaction skills, guidelines for number of treatment hours based on age and school attendance, details about ABA treatment codes that do not differ from CPT standards, requirement for less intrusive behavioral interventions to have been provided prior to ABA, details regarding a provisional ASD diagnosis, requirements to taper ABA after an arbitrary period of time, and details about treatment alternatives. The following assessments were removed from the criteria as acceptable assessments: Verbal Behavior Milestones Assessment and Placement Program (VB-MAPP), Behavior Assessment System for Children (BASC-3), Gilliam Autism Rating Scale (GARS), Assessment of Basic Language and Learning Skills (ABLLS), Achenbach System of Empirically Based Assessment (ASEBA). General information regarding preferences for ABA treatment that would not be considered criteria for medical necessity were also removed from the criteria. A separate document was created with preferences for ABA treatment that all providers will receive a copy of to ensure they are following best practice standards for ABA treatment. The following sections were *added* to the criteria: Criteria for ABA Evaluation, Criteria for Initial ABA Treatment (first 6 months), Criteria for Continued ABA Treatment, and Criteria for Discharge from ABA treatment. Three appendices were added to the criteria with the following titles: Assessment of Symptom Severity – Vineland-3, Assessment of Symptom Severity – ABAS-3, and CPT Code Criteria. Items added to the criteria include: ABA being extended to diagnoses beyond ASD if there is literature to back up its effectiveness, requirement to conduct one of two approved standardized assessments and show impairments of at least 1 standard deviation below the mean, level of impairment driving treatment dosage, assessment of symptom severity, discharge criteria relating to standardized assessment scores, and definitions of meaningful progress in treatment.	

Utilization Management Department
KPCO Criteria for Skilled Therapies for Autism

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Skilled Therapies for Autism

This guideline was developed to support clinician and utilization review teams about appropriate use of **Skilled Therapies for Autism.** It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Skilled Therapies for Autism

Coverage for **Skilled Therapies for Autism** may be considered if ALL of the following are met:

1. Patient has a diagnosis of Autism, Autism Spectrum Disorder (ASD), Asperger's Syndrome, or Atypical Autism in the context of Pervasive Developmental Disorder (PDD).

2. The request is for a covered therapy for ASD and is specific to treating the ASD:
    a. Evaluation and assessment by a skilled rehabilitation provider (RN, PT, OT, ST)
    b. Habilitative or Rehabilitative Care where there is a skilled component,
    c. Pharmacy care and medications that are covered by the patient's plan.
    d. Maintenance therapy or long-term habilitative care when medically necessary to treat ASD
        i. There are no visit limits or age limits for maintenance or long-term therapies related to ASD, as long as the maintenance care is not custodial in nature; this is an exception to the limited duration requirement for other Home-Health services.
        ii. The services must be **medically necessary** for the treatment of the ASD.
        iii. The services must be part of a plan documented by someone with expertise in treating the ASD.
        iv. Since skilled therapy for autism is an exception to the home health rules, OT may be approved as a stand-alone service, when medically necessary.

3. The patient is not a member of a Grandfathered plan under the ACA
    a. Grandfathered plans cover diagnosis and medication management for ASD's, but skilled therapies are subject to the usual Rehabilitation benefit limits, typically 20 visits for each PT, OT, and ST.
    b. QRC will be able to verify Grandfathered vs. Non-Grandfathered plan if a question arises.

4. The patient meets Homebound criteria:

a. A child meets Homebound criteria if either
    i. Accessing facility services is more onerous than a typical child of the same age or developmental stage, taking equipment into account (i.e. leaving home involves a 'considerable and taxing effort' beyond that of a typical child), or
    ii. Is documented as being less effective than in-home therapies.
    iii. Children who qualify under MCG B-806-T Applied Behavioral Analysis for ABA therapies meet the required definition for being "homebound" but must have Hold Code CH143 applied to the referral. This will make the family liable for usual therapy cost-share.

5. The request is NOT for a non-covered service:
    a. Therapies that are not medically necessary for autism but are requested to address a different condition are not included within these guidelines.
    b. "Sensory Integration Therapy" is not covered unless provided by an Occupational Therapist for the purpose of improving self-care and ADL skills only.
    c. Social Skills development is not covered for KPIF Grandfathered Plans only; all other plans cover this when medical necessity is documented.

Regulatory note: The benefits for ASD are in addition to any benefits provided under §10-16-104(1.3), C.R.S., (Early Intervention Services), and §10-16-104(1.3), C.R.S., (Therapies for Congenital Defects and Birth Abnormalities).

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline; input Dr R. Nolan, Developmental Pediatrics and CO-Benefit-Policy Manual section 3B, reference to relevant state statutes. (SB15-015 excludes grandfathered plans)	03.2022
1.1	Title changed to "Skilled Therapies for Autism" removing the word "Rehabilitation". Minor edits providing clarification	09.2023
1.12	Corrected error in title and added language regarding custodial care.	09.2023
1.2	Annual review and minor edits. Hold code clarified and updated	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Use of Autologous Serum Eye Drop Therapy (ASED) for Adults with Severe Dry Eye Disease

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Use of Autologous Serum Eye Drop Therapy (ASED) for Adults with Severe Dry Eye Disease

PROTOCOL:

- Autologous Serum Eye Drops (AESD) may be covered if **ALL** of the following are met:
    - The prescription is written by an Ophthalmologist (MD/DO) or Optometrist (OD)
    - The patient is diagnosed with at least one of the following conditions:
        - Dry Eye Disease noted as clinically “severe”
        - Sjogrens Disease / Keratoconjunctivitis Sicca
        - Graft-Versus-Host Disease
        - Filamentary Keratitis
        - Limbal Stem Cell Deficiency
        - Chemical Keratitis
        - Neurotrophic Keratitis
        - Non-healing Corneal Ulcers
        - Ocular Cicatrical Pemphigoid
        - Mucus Membrane Pemphigoid
        - Complication of Orbital Prosthesis.
    - The patient has failed four times daily dosing of preserved or unpreserved artificial tears for at least two months
    - The patient has failed or is not a candidate for a trial of punctal occlusion, either permanent or temporary.
- Approval may be made for one year.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created ASED Guideline. Consulted with: Anthony Kokx, MD and Todd Theobald, MD, Ophthalmology. Approved by KPCO Guideline Committee on 10/22/18.	10.2018
1.1	Added requirement that the prescription is initiated by Ophthalmologist or Optometrist	01.2019
1.2	Routine update, consulted Dr. G Bang ASC	03.2021
1.3	Routine review, punctal plug update by Dr. T. Theobald	04.2022
1.4	Review update, Consulted Dr. T. Theobald	06.2023
1.5	Approved by: KPCO Utilization Management Committee added	08.2023
2.0	Routine Annual review	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Bariatric Surgery – Commercial Members

Sub department(s): Utilization Management MD	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Bariatric Surgery – Commercial Members

Criteria for Bariatric Surgery

This guideline was developed to support clinician and utilization review teams about appropriate review of bariatric surgical options. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

A patient may qualify for bariatric surgery if EITHER 1 or 2 is met AND if 3 is met:

1. The request is NOT for a non-covered procedure: lap band (gastric band) or intragastric balloon.

2. Initial bariatric surgical procedures are likely to improve long term health outcomes as shown by **ONE** of the following:
    a. *BMI ≥ 39.5 kg/m^2 and above.
    b. *BMI 35-39.4 kg/m^2 and **ONE OR MORE** of the following:
        i. Type 2 diabetes under good control defined as hemoglobin A1C measurement less than 9.0%.
        ii. An obesity related comorbidity is present as shown by **ONE OR MORE** of the following:
            1. Obesity-related pulmonary disease. These might include clinically significant obstructive sleep apnea or obesity hypoventilation syndrome.
            2. Obesity-related cardiovascular disease. These might include coronary heart disease, arrhythmia (e.g. atrial fibrillation), congestive heart failure or obesity related cardiomyopathy.
            3. Hypertension requiring more than one medication to achieve control.
            4. Hyperlipidemia on maximal doses of lipid-lowering medications.
            5. Osteoarthritis of hips or knees in patients who are candidates for joint replacement surgery except for their weight
            6. Pseudotumor cerebri, for which long-term weight loss is indicated, at the recommendation of neurology.
            7. Hepatic steatosis including non-alcoholic fatty liver disease (NAFLD) or non-alcoholic steatohepatitis (NASH).

8. Other obesity-related conditions that, in the opinion of the Bariatric Surgeon and Bariatric Medical Specialist, are felt to be life threatening and for which bariatric surgery can be expected to improve or resolve the condition.
9. Gastroesophageal reflux disease (GERD)

c. BMI 30-34.9 kg/m^2 and **ONE or more** of the following conditions:
   i. Type 2 diabetes with inadequately controlled hyperglycemia (e.g. hemoglobin A1C ≥8.0% despite optimal medical treatment with oral medication and insulin).
   ii. Refractory Gastroesophageal Reflux Disease despite adequate therapy.

3. Repeat bariatric surgery may be indicated if **ANY** of the following are true:
   a. , the patient had a Lap-Band procedure and BMI is ≥ 30.0 kg/m^2 at the time of their request for re-operation, or
   b. The patient suffers from any complication related to a prior bariatric surgery (unacceptable weight loss is not considered a complication).
4. No contraindications to weight loss surgery, as shown by **ALL** of the following:
   a. Diabetes, if present, is well controlled as shown by hemoglobin A1c less than 9.0% immediately prior to the surgical procedure.
   b. No diagnosis of acute or unstable cardiac ischemia or myocardial dysfunction.
   c. No diagnosis of severe chronic obstructive airway disease or respiratory dysfunction, such that any elective surgery would be contraindicated. The presence of treated obstructive sleep apnea is not a contraindication to bariatric surgery.
   d. The patient has shown compliance with medical treatment of obesity or treatment of other chronic medical condition.
   e. No uncontrolled psychological/psychiatric conditions or contraindications to bariatric surgery as documented by a behavioral medicine specialist:
      i. We have received a documented behavioral health assessment that clears the patient, from the psychological/psychiatric standpoint, for bariatric surgery. This clearance must be within 12 months of the scheduled bariatric surgery, unless otherwise stated in the behavioral health note.
   f. No autoimmune or rheumatologic disorders (including inflammatory bowel diseases and vasculidities) that require chronic prednisone therapy.
   g. No hepatic cirrhosis with portal hypertension or ascites.
   h. No coagulopathy (severe protein C or protein S deficiency, homozygous factor V Leiden),
   i. No recent seizures (< 6 months) unless evaluated and cleared by neurology.
5. Determining appropriate venue for Commercial patients.
   a. Gastric Sleeve procedures are <u>outpatient</u> status, unless there is a compelling clinical reason to expect a prolonged hospital stay.
   b. Roux-en-Y, duodenal switch surgery, and all other bariatric procedures are <u>inpatient</u> status.

c. Use of Robotics is permitted for bariatric surgery for commercial members. Robotic equipment is not available at an ASC. From one of our contracted bariatric surgeons: The use of robotics for bariatric surgery is more cost effective than the laparoscopic approach, requires less time in the OR, decreases the patient's length of stay in the hospital, and decreases the surgical complication rates.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Consolidated MCG 23rd Ed, CMS.gov and existing KP CL GL with Drs Adam Tsai and Audrey Bauer	10.2018
2.0	Revised and updated to current evidence, and better alignment with applicable Medicare guidelines	05.2019
3.0	Status updates	10.2019
3.1	Clarification of standards for repeat bariatric surgery	12.2019
3.2	Routine review	02.2021
3.3	Minor language edits	03.2021
4.0	Added statement new statement 1. To indicate noncovered services, added last sentence to 4.c. regarding treated sleep apnea is not a contraindication, changed e. to indicate need for behavioral health clearance note, deleted prior sections e. i-iv, added statement 5.c. for robotic use	06.2023
4.1	Added "duodenal switch surgery" to 5.b.	03.2024
4.2	Routine annual review. No changes made	08.2024

Utilization Management Department
KPCO Criteria for Adolescent Bariatric Surgery

Sub department(s): Utilization Management Medical Directors	Last Review: 02.2024 Next Review: 02.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Adolescent Bariatric Surgery

This guideline was developed to support clinician and utilization review teams about appropriate use of bariatric surgery for adolescents. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Adolescent Bariatric Surgery

Metabolic and bariatric surgery is a proven, effective treatment for severe obesity disease in adolescents and should be considered standard of care. Pediatricians and primary care providers should recognize that children with severe obesity require tertiary care and refer early to the Bariatric program at Children's Hospital of Colorado.

A patient ages 10-17 years 11 months may qualify for bariatric surgery if either 1 or 2 below are met along with 3-5:

1) Body mass index is greater than or equal to 35.0 kg/m2 or 120% of 95%ile AND one of the following major obesity-related comorbidities:
    a) Type 2 diabetes mellitus
    b) Cardiovascular disease risk factors including: dyslipidemia, hypertension or insulin resistance as evidenced by A1C over 5.6 or problem list documenting prediabetes or insulin resistance
    c) Obesity-induced cardiomyopathy as documented on ECHO report
    d) Obstructive sleep apnea AHI >5
    e) Pseudotumor cerebri (e.g. documented idiopathic intracerebral hypertension)
    f) Non-alcoholic steatohepatitis
    g) Orthopedic disease such as SCFE or Blount's Disease
    h) Gastroesophageal reflux disease (GERD)
    i) Polycystic Ovarian Syndrome (PCOS)
2) Body mass index is greater than or equal to 40 kg/m2 or 140% of 95%ile
3) The patient has failed to maintain a healthy weight despite adequate participation in a structured dietary program for 6 months prior to surgery.
4) The patient and caregiver team has completed a pre-operative psychological evaluation that documents ALL of the following elements:

a) Patient can provide assent for the surgical procedure OR if patient has a developmental delay meets criteria developed by ethics team framework or recommended by Hospital Ethics Team review AND the parents or legal guardians give consent

b) Patient and care-giver team can comply with pre- and post-operative instructions.

c) If the patient has history of psychiatric or psychological disorder, the evaluation includes evaluation and assessment of such condition and it is stabilized.

5) Patient has been evaluated by bariatric surgeon and team and deemed an appropriate candidate for surgery with no medical or surgical contraindications

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline. J. Montoya primary author.	09.2019
1.1	Routine review	02.2021
1.2	Routine review	03.2022
1.3	Added line “h” to section (1) after review with CHCO weight loss team	06.2023
1.4	Added (1)(i) and made (3) more concise after discussion with CHCO Medical Director of adolescent bariatric surgery	02.2024

Utilization Management Department
KPCO Criteria for Breast Augmentation for Members Assigned Male at Birth (AMAB) - Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Breast Augmentation for Members Assigned Male at Birth (AMAB)

This guideline was developed to support clinician and utilization review teams about appropriate use of breast augmentation ONLY for members Assigned Male at Birth. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Breast Augmentation for Members Assigned Male at Birth (AMAB)

Breast Augmentation for Members Assigned Male at Birth may be considered if ALL of the following are met:

A. Single letter of referral from a qualified mental health professional, which contains all relevant WPATH required information; and

B. Persistent, well-documented gender dysphoria per DSM-5 criteria for Gender Dysphoric Disorder; and

C. Capacity to make a fully informed decision and to consent for treatment; and

D. Age 18 years or older, or if under 18 on a case-by-case basis as determined by the Gender Health Medical Director; and

E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and

F. BMI is less than 35.0, and

G. Patient is a non-smoker.

H. Twelve months of continuous hormone therapy as appropriate to the member's gender goals, unless contraindicated.
    a. If the referring medical provider or mental health provider requests surgical intervention prior to the patient's completion of 12 months of hormone therapy and/or living in desired gender, the surgeon, the primary care provider, AND the qualified mental health professional must submit evidence of medical necessity and clear rationale for the proposed surgical intervention to be done early. EACH of these three providers must submit written documentation to the plan that includes:

i. A comprehensive, coordinated treatment plan with evidence that all treatment plan criteria for surgery and treatment goals have been met; and
ii. Clear rationale for the variation from either the 12-month period of hormone therapy and/or living for 12 months in desired gender; and
iii. Patient understands the treatment plan, risks and benefits of surgery prior to completing the 12-month period.

I. The patient has not had any prior breast augmentation surgery for any reason; any additional breast augmentation after an initial mammaplasty is considered a cosmetic procedure and therefore a contract exclusion.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline; substance drawn from KPWA and adapted to KPCO needs.	02.2021
1.1	Update to WPATH SOC-8 standards, Dr S. Mason (Gender Health) contributing	01.2023
1.2	Added new F&G (BMI, non-smoker) per updates to Clinical Library toolkit (S.Mason, ed.)	01.2023
2.0	Routine annual review	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Breast Reconstruction after Breast Cancer Surgery

Sub department(s): Utilization Management MD	Last Review: 02.2024 Next Review: 02.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Breast Reconstruction after Breast Cancer Surgery

Criteria for Breast Reconstruction after Breast Cancer Surgery

Reconstructive surgery after mastectomy may be covered if ALL the following are met:

1. The patient has had a unilateral or bilateral mastectomy for breast cancer or breast cancer risk reduction and ANY of the following are met:
   Lumpectomies are not eligible for reconstructive benefit.
   Surgery and reconstruction of the other (non-cancerous) breast is covered in order to produce a symmetric appearance.
   There is no time limit for reconstruction coverage under this section.
   a. For requests to remove excess lateral chest wall skin, there is a documented medical complication apart from cosmetic appearance.
      i. Complications include chronic or recurrent intertrigo or other skin infection, ulceration, or painful skin irritation that has been persistent despite nonsurgical treatment.
      Lateral chest wall skin removal for cosmetic reasons is not covered.
   b. Fat grafting is covered when there is a clearly documented “considerable” tissue defect for which fat grafting is the most reasonable repair option.
   c. Acellular Dermal Matrix (ADM) is covered for ANY of the following conditions:
      i. Implant repositioning,
      ii. Capsular contracture,
      iii. Soft tissue reinforcement or support
      iv. ADM use during primary reconstruction (i.e. during or immediately after mastectomy).
   d. Implant replacement(s) is/are covered for ANY of the following conditions:
      i. Capsular contracture,
      ii. Shell disruption,
      iii. Large seroma,
      iv. Implant malposition.
      Implants are not expected to last indefinitely, repair for these conditions is a covered benefit.
2. The patient does not have any contraindications to plastic surgery, including ANY of the following:
   a. Use of any tobacco products in the 30 days prior to surgery
   b. BMI > 40.0
   c. End Stage Renal Disease (ESRD), GFR < 15.0.
   d. Uncontrolled diabetes, with the last A1C measurement >8.0.

3. The request is not for augmentation prior to mastectomy. Augmentation before mastectomy is not a covered service.

Sources

- Women's Health and Cancer Rights Act (WHCRA)
- Comparative Effectiveness Review of Human Acellular Dermal Matrix For Breast Reconstruction (update 01/27/2019)
- ASC Review (Drs Kiehn, Gerow), June 2019
- ACG A-0498 (Panniculectomy) [for complications requiring surgical intervention].
- NCD N1402v1: NCD Breast Reconstruction Following Mastectomy (140.2) Version 1

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	GL created based on departmental recommendations (Kiehn, Gerow)	07.2019
1.1	Routine review (Dr. Kiehn)	04.2022
1.2	Routine yearly review. Minor edits, added NCD N1402v1 to sources.	02.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Clinical Trial Coverage – Commercial Members

Sub department(s): Utilization Management MD	Last Review: 6.2024 Next Review: 6.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Clinical Trial Coverage – Commercial Members

This guideline was developed to support clinician and utilization review teams about appropriate coverage for Clinical Trial participation for Commercial Members. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Clinical Trial Coverage

General information

1. Procedural code 206756 should be used for all external clinical trial referrals.
    a. CPT code depends on the phase of the trial:
        i. S9988: Phase 1 clinical trial
        ii. S9990: Phase 2 clinical trial
        iii. S9991: Phase 3 clinical trial
2. UMMD to identify the appropriate procedural code when a referral is identified as related to a clinical trial. Sent back to QRC / RN to add to the referral request.

3. A clinical trial is a type of research that studies a test or treatment given to people. Clinical trials study how safe and helpful tests and treatments are. When found to be safe and helpful, they may become tomorrow's standard of care. Clinical trials can study many things, such as:
    a. New drugs not yet approved by the U.S. FDA (**F**ood and **D**rug **A**dministration),
    b. New uses of drugs already approved by the FDA,
    c. New ways to give drugs, such as in pill form,
    d. Use of alternative medicines, such as herbs and vitamins,
    e. New tests to find and track disease, and
    f. Drugs or procedures that relieve symptoms.

4. Per Federal Law, Standard of Care services include ALL of the following:
    a. Costs that would be covered if the member was not participating in the clinical trial,
    b. Items and services required solely for the provision of the investigational item or service, and
    c. Clinically appropriate monitoring of the effects of the item or service or for prevention of complications.

A member may qualify for an initial evaluation for a clinical trial if ALL the following are met:

1. Member has a life-threatening condition documented in the medical record.
2. Member has failed standard therapy for their condition without other reasonable standard therapy options available as determined by member's treating physician(s) and documented in the medical record.
3. The provider or Point of Service (POS) is contracted.

a. Non-contracted providers/POS will be denied as not medically necessary unless reviewed and approved on a case-by-case basis by the UM Clinical Trials Lead Physician and UM Regional Program Director or above.

A member may qualify for Standard of Care (SOC) coverage during a clinical trial if ALL the following are met:

1. The POS is within KP or a contracted POS.
2. Member has a life-threatening condition.
3. Member has failed standard therapy for their condition without other reasonable standard therapy options available as determined by member's treating physician(s) and documented in the medical record.
4. Member must meet the clinical trial entry criteria and have signed consent provided to KPCO.
5. A study calendar is provided OR some clear statement of the Standard of Care services required by the trial.
6. A document outlining what is and is not covered by the study. (example, what medications or laboratory studies are/are not covered).
7. If the Provider or POS is not contracted: the UM Clinical Trials Physician Lead has reviewed the clinical trial and prepared a Standard of Care coverage agreement that has been reviewed and approved by UM Regional Program Director or above.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline (J.Ley), approval through UM leadership	03.2020
1.1	Routine review.	02.2021
1.2	Added requirement for NCT title and identifier be listed on the referral for evaluation	12.2021
1.3	Routine review	01.2024
1.4	Deleted line 3 under Initial Criteria requiring Clinical trial title and identifier number for initial evaluation	06.2024
1.4	Minor edit to correct spelling error	07.2024

Utilization Management Department
KPCO Criteria for Coverage of Early Intervention Services

Sub department(s): Utilization Management Medical Directors	Last Review: 10.2024 Next Review: 10.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Coverage of Early Intervention Services

This guideline was developed to support clinician and utilization review teams about appropriate use of **Early Intervention Services.** It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Coverage of Early Intervention Services

Coverage of Early Intervention Services may be considered if ALL of the following are met:

1. The child has not yet reached their 3rd birthday.
    a. EIS is not available to children over 3 years old.
2. For an initial request, EIS provider supplies written parental consent to use private health insurance.
    a. From: section 7.912.C.4 and E.2.a.
3. For a request increase the frequency, duration, or intensity of EIS services, provider must again provide written parental consent for such changes.
    a. From: 7.912.E.2.b.
4. The request includes only covered services, which are ONLY these:
    a. PT, OT, ST, including use of assistive technologies
    b. Audiology
    c. Developmental intervention Services
    d. Skilled nursing care
    e. Nutrition (RD)
    f. Psychology, including social and emotional assessments.
    g. Sign language services
    h. Vision training

5. The EIS provider includes a complete Individualized Family Service Plan, which includes all of the following (7.920.F.3):
    a. Name and discipline of each individual participating in the evaluation and assessment
    b. Evaluation instrument(s), child assessment tool(s), and methods and procedures used to conduct the evaluation and assessment
    c. The measurable results of the multidisciplinary evaluation and/or assessment in each of the developmental domains
    d. Statement of eligibility or ineligibility.

e. Signature of a parent acknowledging that he or she has been informed of his or her child's eligibility determination.

6. Services do not overlap or duplicate other therapy services the member is already receiving. Member may receive services through EIS and insurance plan if the service does not overlap (i.e.. Is treating a separate condition).

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, citations to Colorado statute: Early Intervention Program 12 CCR 2509-10; references to subsections thereof.	03.2022
1.1	Minor edits, annual review	10.2023
1.2	Rediscussed if overlapping services are permitted and determined this is not permitted but can be considered on and individual basis when the service is not offered within EIS or is less effective. Wording updated.	09.2024
1.3	Annual review. No changes made	10.2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria:

Determining Appropriate Surgery Venue

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

General Guidelines

Authorized outpatient procedures are appropriate in a hospital setting when one or more of the following criteria are met:

1. Patient weighs more than 400 pounds or has a BMI greater than or equal to 50
    a) Patient BMI ≥ 45 but <50 requires Anesthesiologist review
2. Post-operative ventilation due to the procedure or pre-existing health condition is anticipated.
3. Extensive blood loss requiring blood transfusion is anticipated.
4. Patient is an adult who meets the guidelines specific to ASA IV.
    a) See "Acceptable Surgeries for ASA IV Adult Patients" for exceptions
5. Case is emergent/life threatening.
6. ASC does not have appropriate surgical equipment access for the scheduled procedure.
7. Major or prolonged invasion of body cavities is anticipated.
8. Involvement of major blood vessels is required.
9. Transfer of patient to another facility is planned or anticipated.
10. Patient has an existing, Abdominal Aortic Aneurysm (AAA) that is greater than 4.9 cm in diameter.

ASC VENUE FOR TOTAL JOINT REPLACEMENT

Authorized outpatient procedures are appropriate in a hospital setting when one or more of the following criteria are met:

1. Noted as "complicated" procedure by orthopedic surgeon
2. Age ≥ 76yrs
3. BMI > 37.5 kg/m2
4. Hemoglobin ≤ 12 g/dL
5. Current Seizure Disorder diagnosis

6. Active treatment for any liver disease.
7. GFR $\leq$ 60
8. HgA1C $\geq$ 8.0
9. Alcohol or Opioid Substance Use Disorder
10. Current use of walker or wheelchair
11. Disabled or on SSDI

Conditions requiring Anesthesiologist review and permission before being authorized for ASC venue

1. ASA 4
2. Chronic Opioid Use
3. Any ASC exclusion factor above.

Acceptable Surgeries for ASA IV Adult Patients at ASC

1. Only local anesthetic with minimal sedation is planned.
2. No patient with respiratory distress; patients requiring routine oxygen acceptable.
3. No patient with an internal cardioverter-defibrillator (ICD) requiring electrocautery.
4. Acceptable surgeries:
    a. Corneal transplant.
    b. Cystoscopy.
    c. Hand or foot surgery (minor).
    d. Lumpectomy.
    e. Neuroma removal (hands or feet).
    f. Oculoplastics.
    g. Plastic surgery (minor).
    h. Trabeculectomy.
    i. Vitrectomy (retrobulbar anesthesia ok).

Classification

ASA Classification for Adult Patients (Age 16 and over)

- **ASA I Patients:** These patients are healthy with no heart, lung, kidney, or liver disease.
- **ASA II Patients:** These patients have mild, systemic disease. Examples: smokers with mild lung disease, non-insulin dependent diabetics, and well-controlled hypertension.

- **ASA III Patients:** These patients have a systemic disease that restricts daily activities, but not incapacitating. Examples: insulin-dependent diabetics, mild COPD (not on oxygen at any time), stable angina (chest pain only with vigorous activity), poorly controlled hypertension, implanted pacemaker, distant history (> 6 months) of MI, CVA, and/or TIA.

- **ASA IV Patients:** These patients' disease is a constant threat to life. Examples: COPD patients (oxygen dependent at any time), clinical signs of CHF (ankle edema, shortness of breath), cannot climb one flight of stairs or walk from a car to a building without becoming short of breath, unstable angina (chest pain at rest), end-stage renal disease (on dialysis), history of an MI, CVA, TIA (< 6 months), ejection fraction less than 35%, respiratory distress at rest, and uncontrolled diabetes

ASA Classification for Pediatric Patients (Age 15 and under)

- **ASA I Patients:** These patients are healthy with no heart, lung, kidney, or liver disease.

- **ASA II Patients:** These patients have mild, systemic disease. Examples: non-insulin dependent diabetics, insulin dependent diabetics with **good** blood sugar control over the past year, obesity, well-controlled asthma (not needing ER visit within the past year), valvular heart disease which has been surgically corrected, and history of sleep apnea.

- **ASA III Patients:** These patients have a systemic disease that restricts daily activities, but not incapacitating. Examples: insulin-dependent diabetics with **poor** blood sugar control over the past year, morbid obesity, poorly-controlled asthma (needing ER visit within past three months), symptomatic valvular heart disease (i.e. cyanotic with exercise), dwarfism, airway abnormalities, and history of CHF (controlled with diuretics).

Ambulatory Surgery Center Admissions

Admissions: All persons admitted to the ambulatory surgical center shall be under the direct care of a member of the provider staff. The provider staff shall ensure the continuity of care for each patient including pre-operative, intra-operative, and post-operative care. Each patient shall be provided prior to admission all necessary instruction and education for pre and post-surgical care.

1. Restrictions: Surgical procedures shall be limited to the following: Those that do not exceed twenty-three (23) hours combined operating and recovery and/or convalescent time, and; Those that do not generally result in extensive blood loss, directly involve of major blood vessels, constitute an emergency or life threatening procedure, or there is no anticipated major or prolonged invasion of body cavities.

2. Identification: Each patient admitted to the center shall have a visible means of identification placed and maintained on his/her person until discharge. In cases of off-site pre-planned transfer such means of identification shall be maintained throughout the period of transfer and until such time as the patient becomes a patient of another licensed facility.

3. Admission Requirements: All admissions shall be in accordance with appropriate written policies and procedures which reflect the admission requirements established in this section, recommended by the provider staff and adopted by the governing body, specific to the ambulatory surgical center operations, that includes at least the following:

    - The physicians performing the procedure shall document in writing that the patient is in good health or that any pre-existing health conditions are adequately controlled, require no special management and are such that performance of the procedure in an ASC, rather than a hospital setting, does not pose an increased risk to the patient.

- The patient or a responsible person acting on behalf of the patient must be able to strictly follow instructions related to ingestion of fluids or solids within the specified time frame prior to the surgery.
- If the patient is to receive sedation or anesthetic which will result in impaired mental status following surgery, the patient must be accompanied upon discharge by a responsible adult.
- Patients who may require post-operative ventilation following surgery, either because of the procedure to be performed or because of a pre-existing condition, shall not be admitted for surgery.
- Surgery which requires the presence of special equipment, personnel, and/or facilities due to the risk of the operation involved shall not be performed in the center unless such equipment, personnel, and/or facilities are available in the ambulatory surgical center.
- When overnight care is provided, appropriate services shall be rendered within the defined capabilities of the organization. If overnight care is to be provided by the facility, notice of such shall be sent to the Health Facilities Division.
- The governing body of the facility shall have an organization wide policy on the use of smoking materials in the facility which shall be posted and disclosed to the patient upon admission.

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline from existing KASC / LT ASC guidelines and addition of Shoulder Arthroplasty (Dr. Skaife contributing)	08.2021
1.1	Language update for clarity.	09.2021
1.2	Updated language to clarify HOP/22 venue and use of 'continuous' oxygen therapy.	12.2021
1.3	Minor edits per 4/11/2022 email from department	05.2022
1.4	Removed smoking status and insulin use as exclusions per email Dr. D. Brown LTASC director 2/9/23	03.2023
1.5	Routine review. No changes made	06.2023

2.0	Updated the example list in the first bullet point, minor adjustment to wording on 2nd bullet, deleted the 80 year-old age limit for shoulder arthroplasty on 4th bullet, minor wording change on bullet 6, changed hgbA1c from <7 to <8 on bullet 9, deleted "No history of DVT, PE, TIA/stroke, MI, or other thromboembolic event *except* for shoulder arthroplasty: a provoked lower extremity DVT does not disqualify a shoulder replacement from ASC status," added "No history of Opioid Substance Use Disorder," added "Patients with chronic opioid use (>6 months) must be reviewed and approved by an anesthesiologist," deleted "No history of significant nausea with opiate use" section, deleted "Not immunocompromised or taking immunomodulatory medications" section. – updates made per email from KP Orthopedic surgery medical director, Dr. James Macdougall	08.2024
2.1	Routine annual review. Incorporated into the broader Determining Appropriate Surgery Venue guideline.	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Adult Facet Joint Intervention Guidelines (Commercial Members)

Sub department(s): Utilization Management MD	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Adult Facet Joint Intervention Guidelines (Commercial Members)

This guideline was developed to support clinician and utilization review teams about the appropriate use of facet joint interventions for pain management. This guideline is not intended to replace a clinician's judgement or to establish a protocol for all patients with a particular condition.

Facet interventions for pain management may be approved in <u>ALL</u> the following are met:

1) Chronic (at least 3 months) duration of spinal pain originating from **<u>1 or more</u>** of the following regions:
   a) Cervical
   b) Thoracic
   c) Lumbar

2) Failure of at least 6 weeks of nonoperative management, as indicated by **<u>1 or more</u>** of the following:
   a) Exercise program
   b) Pharmacotherapy
   c) Physical therapy
   d) Spinal manipulation therapy

3) Absence of untreated radicular pain in same spinal region

4) The procedure may be approved if **<u>1 or more</u>** of the following are met:
   a) Diagnostic block may be performed if either:
      i) Initial diagnostic block to diagnose facet mediated pain, OR
      ii) Second confirmatory diagnostic block (dual diagnostic blocks are necessary to diagnose facet pain) if documentation indicates first diagnostic block produced 80% or greater relief of primary (index) pain and duration of relief is consistent with agent used;
      AND
      iii) Medial branch block is performed for block unless specific clinically documented reason medial branch block cannot be performed
   b) Therapeutic facet intra-articular injection may be performed as **<u>1 or more</u>** of the following:
      i) Initial injection, as indicated by **<u>ALL</u>** the following:

(1) Patient has had 2 medically reasonable and necessary diagnostic facet joint procedures.
(2) Each diagnostic procedure provided at least 80% relief of primary (index) pain, and duration of relief was consistent with agent used.
(3) Documentation of why patient is not candidate for radiofrequency ablation (RFA) (such as established spinal pseudarthrosis, implanted electrical device)

ii) Subsequent injection at same anatomic site, as indicated by **ALL** the following:
(1) Patient met criteria for initial therapeutic facet joint injection.
(a) Initial therapeutic joint injection was effective, as indicated by **1 or more** of the following:
(i) Patient experienced at least 50% pain relief for at least 3 months from prior therapeutic procedure.
(ii) Patient experienced at least 50% improvement in ability to perform functional tasks and ADLs as compared to baseline measurement using same scale.
(2) Patient has not had more than 3 therapeutic facet joint (IA) sessions per covered spinal region performed in prior rolling 12 months.

c) Therapeutic radiofrequency ablation (RFA) may be performed as **1 or more** of the following:
i) Initial RFA may be performed if **ALL** the following:
(1) Patient underwent 2 diagnostic facet blocks each with a positive response
(2) Positive response to diagnostic block by experiencing either:
(a) Patient experienced at least 80% pain relief during the anesthetic phase
(b) Patient experienced at least 50% improvement in ability to perform functional tasks and ADLs as compared to baseline measurement using same scale
ii) Repeat RFA may be performed at the same spinal level(s) when there is a prior history of successful facet radiofrequency ablation (50% or more reduction in pain documented for at least 6 months)

d) Intra-articular facet joint injection with synovial cyst aspiration, as indicated by **1 or more** of the following:
i) Initial procedure, as indicated by **ALL** the following:
(1) Advanced diagnostic imaging study confirms compression or displacement of corresponding nerve root by facet joint synovial cyst.
(2) Clinical and physical symptoms related to synovial facet cyst are documented in medical record.
ii) Single repeat cyst aspiration/rupture for patient who experienced at least 50% or more consistent improvement in pain for at least 3 months

5) Facet interventions are considered medically necessary and reasonable if **ALL** the following:
a) No active infection is present
b) There is no additional neurologic or musculoskeletal pathology to cause pain (vertebral fracture, other neurologic disease, infection, significant deformity)
c) No interventions are performed at multiple spinal regions during the same session
d) Facet interventions may not be combined with other procedures (trigger point injections, peripheral joint injections, epidural steroid injection unless treatment for facet synovial cyst with radiculopathy)
e) No more than 1-2 spinal levels treated unilaterally or bilaterally at a spine region session
f) No more than 1 session may be performed at each spine region each 3 months

References:

- Sources: MCG (Milliman Care Guidelines) 23rd Edition Guidelines A-0695, A-0218.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created Adult Facet Joint Injection and Neurotomy Guideline. Consulted with Jeff Glaves, MD, Mike McCeney, MD & Christine Munson MD, Physiatry and RSC of the Department of Neurosurgery..	01.2018
1.1	Updated for consistency with Medicare GL. Reviewed with C.Munson MD RSC.	04.2019
2.0	Updated based on new LCD update (8/22/19update) [removed pain aggravated by movement of spine. Reduced noninterventional treatment to 6 weeks per LCD. Updated rhizotomy GL for Medicare]	10.2019
2.1	Routine review. Minor edits.	11.2020
2.2	Routine review.	02.2021
2.3	Routine review.	04.2022
2.4	Remove Medicare-only section; compliance advises using NCD/LCD directly.	01.2023
3.0	Neurosurgery Chief reviewed existing guideline and reworded, reordered the majority of it so it reads better and easier to understand. There is some added language.	06.2023
3.1	Routine annual review. No changes needed, per KP Neurosurgery medical director, Dr. Christopher Kudron	08.2024

Utilization Management Department
KPCO Criteria for Gender Affirming Body Contouring Procedures - Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Gender Affirming Body Contouring Procedures

This guideline was developed to support clinician and utilization review teams about appropriate use of **Gender Affirming Body Contouring Procedures.** It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

There is a lack of evidence that body contouring affects psychological functioning and quality of life outcomes, and there are numerous naturally occurring variations in body habitus among cis- and trans-feminine and masculine patients related to genetics, age, BMI, hormone response, and other factors. Existence of this guideline in no way guarantees coverage for any of these procedures.

Criteria for Gender Affirming Body Contouring Procedures affecting the soft tissues of the abdomen, flanks, and hips.

Approval for gender-affirming body contouring procedures may be considered if ALL of the following are met:

1. Age 18 years or older; and
2. Ask QRC to perform Benefit Check and confirm that member has benefit coverage for the requested procedures, and
3. The request is for surgery affecting soft tissues of abdomen, flanks, and/or hips, and
4. Single letter of referral from a qualified mental health professional, which contains all relevant WPATH required information; and
5. There is persistent, well-documented gender dysphoria per DSM-5 criteria for Gender Dysphoric Disorder in the medical record; and
6. Capacity to make a fully informed decision and to consent for treatment; and
7. If significant medical or mental health concerns are present, they must be documented as reasonably well controlled; and
8. The patient has completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless medically contraindicated; and
9. Patient has a stable BMI <30 because weight loss affects body fat distribution in a meaningful way, and
10. The request is not for alterations to the bony skeleton, and
11. The request is not to alter appearance or to augment (using implants or fat transfer) body areas that appear with in the normal range for the patient's gender identity.

Covered CPT codes include these:

15877 Suction assisted lipectomy; trunk

15847 Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen

15771 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate

15772 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, Drs. S. Mason (Gender Health), C. Ligh (Plastic Surgery) contributing; KP SCAL Guideline used for reference.	01.2023
1.1	Routine maintenance, clarification for Commercial only.	04.2024
1.2	Revision made to add in that member must have benefit coverage for the requested procedures	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Gender-Affirming Care for CHP+ Members

Sub department(s): Utilization Management MD	Last Review: 11.2023 Next Review: 11.2024 Approved by: Utilization Management Guideline Committee

Title:
KPCO Criteria for Gender-Affirming Care for CHP+ Members

This guideline was developed to support clinician and utilization review teams about the appropriate use of gender-affirming care for Children's Basic Health Plan (CHP+) members. This guideline is not intended to replace a clinician's judgement or to establish a protocol for all patients with a particular condition.

Children's Basic Health Plan (CHP+) now covers the same gender-affirming care services as Health First Colorado's coverage updates that are effective August 30, 2023.

Covered services include behavioral health, hormone therapy, and surgical procedures.

Gender-affirming care for CHP+ members may be considered if <u>ALL</u> the following are met (member eligibility criteria):

1) Member has a clinical diagnosis of gender dysphoria,
2) Requested service is medically necessary,
3) Any co-existing physical and behavioral health conditions do not interfere with diagnostic clarity or capacity to consent, and associated risks and benefits have been discussed,
4) Member has given informed consent for the service, and, subject to the exceptions regarding emancipated minors in C.R.S. § 13-22-103, if the member is under 18 years of age, member's parent(s) or legal guardian has given informed consent for the service.

Nonsurgical Gender-Affirming Interventions

Behavioral Health:

1) Primary diagnoses codes: F64.0-F64.9
2) Prior Authorization is required for these services:
   a) 96121*, 96130-96133*, 96136-96139*, 96146*,
   b) 97535*, 97537*,
   c) G0176*, G0177*,
   d) H0015*, H0017-H0019*, H0035*, H0044*, H2012*, H2036*,
   e) S5150*, S5151*, S9480*

Hormone Therapy:

Prior to beginning gender-affirming hormone therapy, a licensed health care professional who has competencies in the assessment of transgender and gender diverse people must determine that any behavioral health conditions that could negatively impact the outcome of treatment have been assessed and the risks and benefits have been discussed with the member, and

For the first twelve (12) months the gender-affirming hormone therapy member must receive medical assessments at a frequency determined to be clinically appropriate by the prescribing provider.

1) Gonadotropin-releasing hormone therapy (GnRH) may be considered if **ALL** the following are met:
   a) Meets the Member Eligibility criteria listed above (Eligibility Criteria 1-4),
   b) Meets the applicable pharmacy criteria at section 8.800, and,
   c) Has reached Tanner Stage 2 or greater.
2) Gender affirming hormone therapy may be considered if **ALL** the following are met:
   a) Meets the Member Eligibility criteria listed above (Eligibility Criteria 1-4),
   b) Meets the applicable pharmacy criteria at section 8.800,
   c) Has been informed of the possible reproductive effects of hormone therapy, including the potential loss of fertility, and the available options to preserve fertility,
   d) Has reached Tanner Stage 2 or greater, and
   e) If under 18 years of age, demonstrates the emotional and cognitive maturity required to understand the potential impacts of the treatment.

Surgical Gender-Affirming Interventions

Gender-affirming surgery means a surgery to change primary or second sex characteristics to affirm a person's gender identity. This is known as gender confirmation surgery or sex reassignment surgery.

Requests for medically necessary gender-affirming surgeries will be reviewed by the Utilization Management team. CHP+ covers medically necessary gender-affirming surgical procedures on genitals, chest, neck, and face in accordance with generally accepted standards of medical practice.

Gender-affirming surgery for CHP+ members may be considered if ALL the following are met:

1) Meets the Member Eligibility criteria 1-4 listed above,
2) Is 18 years of age or older,
3) Has completed six (6) continuous months of hormone therapy, unless hormone therapy is not clinically indicated or is inconsistent with the client's desires, goals, or expressions of individual gender identity,
    a. This requirement does not apply to mastectomy surgeries,
    b. Twelve (12) continuous months of hormone therapy are required for mammoplasty, unless hormone therapy is not clinically indicated or is inconsistent with the client's desires, goals, or expressions of gender-identity,
4) Understands the potential effect of the gender-affirming surgery on fertility

Non-Covered Surgical Services:

The following services are **NOT** covered under the gender-affirming care benefit:

1) Reversal of covered surgical procedures
2) Any items or services excluded from coverage under 10 CCR 2505-10 8.011.1, which are general payment exclusions from the CHP+ program. This includes things such as
    a. Items and services that might support the personal comfort of the member but are not necessary to diagnose or treat an illness or injury or to support the function of a malformed body member,
    b. Items and services for which there is not a legal obligation to pay (i.e offered as free),
    c. Items and services paid for by another governmental entity, or
    d. Items and services provided outside the United States.

References:

- Sources: The Colorado Department of Health Care Policy and Financing
- [1] Health First Colorado Gender-Affirming Care Billing Manual: https://hcpf.colorado.gov/gac-manual
- [2] Health First Colorado Behavioral Health Billing Manual: https://hcpf.colorado.gov/sites/hcpf/files/July%202023%20USCS%20Manual%20Draft%20-Final.pd

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created the KPCO Criteria for Gender Affirming Care for CHP+ Members based on the Colorado Department of Health Care Policy and Financing changes to gender-affirming services coverage for CHP+ members.	11.2023

Utilization Management Department
KPCO Criteria for Gender Affirming Facial Surgery - Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Gender Affirming Facial Surgery

This guideline was developed to support clinician and utilization review teams about appropriate use of **Gender Affirming Facial Surgery**. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Gender Affirming Facial Surgery

Gender Affirming Facial Surgery may be considered if ALL of the following are met:

1. Member has Persistent, well-documented gender dysphoria per DSM-5 criteria for Gender Dysphoric Disorder; and

2. Ask QRC to perform benefit check. Member must have gender affirming facial surgery benefit for the procedures being requested.

3. Age 18 years or older, or if under 18 on a case-by-case basis as determined by the Gender Health Medical Director; and

4. Single letter of referral from a qualified mental health professional, which contains all relevant WPATH required information; and

5. Capacity to make a fully informed decision and to consent for treatment; and

6. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and

7. Six months of continuous hormone therapy as appropriate to the member's gender goals unless contraindicated.

8. BMI is less than 40.0

9. Patient is a non-smoker.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, content from Dr. S. Mason, Gender Health Medical Director; input from Dr. M. Kiehn (Plastics) and K. Motamehdi (ENT)	03.2022
1.1	Updated to “gender affirming” from “feminizing” in anticipation of Colorado regulatory changes.	04.2022
1.2	Update to WPATH SOC 8 criteria, Dr S. Mason (Gender Health) contributing.	01.2023
1.3	Added 7 and 8 to align with gender health toolkit article (updated by S.Mason)	01.2023
1.4	Routine maintenance, clarify that this is for Commercial only	04.2024
1.5	Updated to add the criteria that Member must have benefit	09.2024
1.6	Updated the team who can do a benefit check of the EOC	09.2024

RESOURCE STEWARDSHIP
Genetic Testing Review Process

Sub department(s): Utilization Management MD	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO UM Committee

Title:
Genetic Testing Review Process

This process document was developed to support clinician and utilization review teams about appropriate means for reviewing genetic testing request. It is not a guideline. Guidelines to be used for specific types of genetic testing requests are included in each subjection.

Criteria for Genetic Testing Reviews

Reviews are performed by the UM Medical Director(s) reviewing Commercial or Medicare cases for a particular day.

1. Medicaid Members: Requests for a Medicaid members should be returned to lab for cancellation. We cannot approve or deny tests for Medicaid members because KFHP-CO is not the payer.

2. Non-Contracted Labs: Consult requests from KP Lab will always be to a contracted external lab, or it will be very obvious that the lab is not contracted.
    a. Requests from Network providers (usually have come in via fax and through RN review) should be reviewed to determine if there is a contracted lab that performs a similar test—contracted labs are listed in the UM Resource Guide. If there is a contracted lab available for similar or identical testing, deny for non-contracted POS. If there is no contracted lab that can perform the test, review for medical necessity in the usual fashion (see below) and approve or deny based on medical necessity.
3. Commercial Plans:
    a. Requests from KP Oncology:
        i. Start with KP ordering guidelines: https://cl.kp.org/natl/pathways/oncology/mg/index.html. Approve if the request meets one of the protocols on this list.
        ii. Open the patient's chart and find the progress note entry with the lab request.
        iii. You may need to click on the Clinical Documentation note from department Genetics to see the Informed DNA genetic counselor notes and rationale for testing.
            1. This is usually a note from **InformedDNA** and is an attachment to the Clinical Documentation note.
        iv. Review for reasonableness and, if applicable, guidelines from our usual evidence aggregators: MCG, Hayes, ECRI.

b. Requests from KP Genetic Counselors (currently Nicky Stopa, Haley Kletke, Sandra Linn, and Jon Saari): Review for reasonableness and, if applicable, guidelines from our usual evidence aggregators: MCG, Hayes, ECRI.
c. Requests from Other Specialists:
    i. Medical or Surgical Specialist may order testing with their specialty (e.g. GYN for BRCA testing), otherwise need genetic counseling first. This is true for contracted NoCo /SoCo providers as well.
    ii. UCH Adult Genetics, Dr Matt Taylor, may be approved if medically necessary even without counseling.
    iii. Sandra Linn and Jonathan Saari are our genetic counselors working with KP Perinatology.
    iv. Review for medical necessity. If no support in KP Oncology Pathways (on clinical library), MCG, Hayes, or ECRI- deny as "experimental and/or unproven."
        1. Use the Benefit Denial genetic testing note in the UMMASTER.
d. Requests from Primary Care (FM, IM, Peds):
    i. These require documentation of genetic counseling. Review Heath Connect and Care Everywhere for notes from Genetics or a specialist. If supporting documentation is not found, deny for "genetic counseling not performed".
e. Review requests for medical necessity, compare KP Oncology pathways (clinical library), MCG, Hayes, ECRI (in that order).
    i. If there are no supporting documents to approve or deny based on MCG, Hayes, or ECRI then consider reviewing the Lab's website for information.
    ii. If the request is for a panel of genes that there is not a guideline found and criteria is met for some of the genes or a narrower panel, approve for the broader panel. Panels are often much more cost effective. (You can go to the laboratory website for information on what genes are in the panel request if this is not specified in the referral or genetic counsellor's note).
    iii. If you approve, routing depends on the source of the referral:
        1. For referrals that came from **outside** KP use the Approve note in the UMMASTER dot-phrase and send to MD Approve – pend to CRC like any other approval.
        2. For referrals that came from **inside** KP (those that were sent to UMMD directly by lab) use the **Approve Internal Request for Genetic Testing** note and send to CRC, who will then pend to Patient Financial Services.
    iv. If you deny, use UMMASTER and send to "**MD Denial – pend to Regulatory**." The dot-phrase includes instructions for routing to lab so the order can be cancelled.
        1. There are two options: "no guideline / benefit denial" and "guideline not met / medical necessity denial."

4. Pediatric patients:
    a. Requests from KP Developmental Pediatrics (Dr. Robyn Nolan) are typically going to be

approved, however, do a quick review for medical necessity and message Dr. Nolan if the request is not understood or why it meets medical necessity if this is not clear – approve if medical necessity is met.

b. Requests from CHCO via Affiliate Link (AFL) need to be reviewed for medical necessity.
    i. The test requests from CHCO genetics are entered by Dr. Christine Jelinek, however, the review for medical necessity is done by the UM team. You can outreach to Dr. Jelinek for help with your review for medical necessity if needed.
    ii. If a broad panel is ordered and a staged approach to testing is appropriate, consider splitting the referral and authorizing only what is medically necessary for the first stage of testing. A request can later be submitted for additional testing if indicated based on the results of initial testing.
    iii. Approve if medical necessity is met or Deny as "experimental and/or unproven" if no support in MCG, Hayes or ECRI.

5. Medicare Reviews**:** may start with KP Oncology Pathways:
    i. https://cl.kp.org/natl/pathways/oncology/mg/index.html. Approve if the request is allowed by these protocols.
    ii. May approve based on this guideline but never deny.
b. review NCD/LCD next (may use MCG website for NCD/LCD text):
    i. **Panel testing**: determine if the panel test has an NCD and if so, review under that NCD.
    ii. If there is no NCD for a **panel** test, or if it is a request for **testing not part of a panel**, see if the test has an LCD from the jurisdiction the laboratory headquarters are in.
    iii. If the panel has an LCD then the jurisdiction in which the Lab is located determines coverage for the panel.
        1. Ambry: SoCal
        2. Ariosa: NoCal
        3. ARUP: Utah
        4. Athena: Massachusetts
        5. Fulgent: SoCal
        6. GeneDx: Maryland
        7. Genomic Health (Exact Sciences): NoCal
        8. Invitae: NoCal
        9. Mayo: Minnesota
        10. Myriad / Counsyl: Utah
        11. If there is no LCD for the lab jurisdiction then look for an LCD for Colorado.
    iv. If a contracted lab can perform a substantially similar test send to RN to see if provider will change to the contracted lab. If provider will not change to a contracted lab **approve** if met, otherwise **deny**.
        1. For Medicare we are not able to deny as “provider not contracted” if there is only one lab that performs the test and there is an LCD from that lab’s jurisdiction and the guideline is met for the LCD.

c. If there is not an LCD specific to the test request, use **L35396, L35062, or L36715** from Novitas as a guideline to which tests are covered in which circumstances.
d. If the test is not in one of the listed LCD's, review the general NCD 90.2 for general rules on genetic testing. **Approve or Deny** based on those strict criteria.
    i. NCD 90.2 is a very general genomic testing NCD.
    ii. This is a peculiar situation where the LCD should be reviewed before the NCD; the LCD authors are obligated to ensure the LCD fulfills NCD requirements while expanding on them.
    iii. This is why we review NCD after the relevant LCD, which is different than the usual order.
e. If there is no LCD or NCD or criteria are not met, may use MCG – Hayes – ECRI (in that order) to review for medical necessity and **approve or deny** based on those criteria.
f. When no guideline exists, default to what makes most clinical sense. We can use other reputable sources such as Up To Date to approve but need something more directly on point to deny.

Contracted labs for genetics (Resource Guide may be more up to date): Ambry - Ariosa - ARUP - Athena - Biocept (liquid cancer/serum genomics) - Blueprint Genetics - Counsyl - Fulgent - GeneDx - Genomic Health (OncotypeDx Breast, Colon, Prostate, see separate entries) - Halio - Illumina (prenatal) - Integrated Genetics - Invitae - Mayo - Monogram Biosciences (HIV) - Myriad - Prevention Genetics - Prometheus - STRATA (tumor NGS) - Tempus - UCSF Dermatopathology - Quest. Ambry & Invitae are now preferred for genetic testing. Tempus is preferred for NGS.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline	01.2020
2.0	Update based on operational process changes	03.2022
2.1	Clarified routing for internal vs external referrals	07.2022
2.2	Routine Review	06.2023
2.3	Routine review, clarification as process document, not a guideline	04.2024

Utilization Management Department
KPCO Criteria for Home Health Care Utilization

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved By: KPCO Utilization Management Committee

Title:
KPCO Criteria for Home Health Care Utilization

This guideline was developed to support clinician and utilization review teams about appropriate use of Home Health services. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Home Health Care Utilization

We cover skilled nursing care, home infusion therapy, physical therapy, occupational therapy, speech therapy, home health aide services, and medical social Services:

1. only on an Intermittent Care Basis; and

2. only within our Service Area; and

3. only to an eligible Member(s) when ordered and provided by a Plan Provider or self-administered. Care must be provided under a home health care plan established by the Plan Provider and the approved home health services provider; and
4. only if a Plan Provider determines that it is feasible to maintain effective supervision and control of your care in your home; and
5. If the member is home bound (confined to the home) per Medicare criteria; BOTH of the following must be met:
    a. Because of illness or injury, the individual needs the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person to leave their place of residence, or
        i. Have a condition such that leaving his or her home is medically contraindicated.
    b. AND there must be a normal inability to leave the home and leaving home must require a considerable and taxing effort.

6. Services are reasonable and necessary, as defined by the relevant KPCO or MCG guideline for home health services.

<u>Home Health Care Exclusions:</u>

7. Services are skilled in nature and not custodial care.

    a. CMS defines custodial care as “any non-medical care that can reasonably and safely be provided by non-licensed caregivers…. [and] involves help with daily activities like bathing and dressing.”
8. Homemaker Services
9. Services that the Health Plan determines may be appropriately provided in a Plan Facility or Skilled Nursing Facility if we offer to provide that care in one of these facilities.
10. The request is not solely for Occupational Therapy, Social Work, and/or Home Health Aide services. These services are potentially available, subject to medical necessity requirements, as adjunctive to covered Skilled Nursing, Physical Therapy, or Speech Therapy services but are not covered absent a covered SN, PT, or ST skilled need.

11. Request for Services does not exceed the following allowed amounts:
    a. Up to 15 visits and 30 days, for approval by RN reviewers based on their guidelines regarding medical necessity.
    b. Any reasonable number of visits but not greater than 60 days’ duration (one certification period) for Physician reviewers.
    c. Daily insulin: Not greater than once a day insulin administration and 60 days’ duration (one certification period) for Physician reviewers.
    d. Services in excess of these limits are likely to fail the part-time, intermittent requirement for Home Health services and/or be custodial in nature and will be denied.
    e. CMS rules allow for “extensions in exceptional circumstances when the need for additional care is finite and predictable”

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created	01.2021
1.1	Routine review	04.2022
1.2	Update: OT, SW, HHA cannot be standalone services (point 10 added)	07.2022
1.3	Routine review by Dr. Swan Davis, D.O., UMMD	08.2023
1.4	Routine annual review. No changes needed	08.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Home Phototherapy ("light box" therapy)

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Home Phototherapy ("light box" therapy)

Criteria for Home Phototherapy ("light box" therapy)

Home UV equipment ("light box" therapy) is covered when ALL the following conditions are met:

- A dermatologist has ordered this device.
- The patient has one or more of the following conditions:
  - generalized pruritus
  - mycosis fungoides (a type of cutaneous lymphoma)
  - prurigo nodularis
  - palmoplantar pustulosis
  - urticaria, pityriasis rubra pilaris
  - seborrheic dermatitis (dermpal very helpful for bad seb derm)
  - lichen sclerosis,
  - moderate to severe psoriasis,
  - vitiligo,
  - eczema,
  - lichen planus,
  - atopic dermatitis,
  - idiopathic dermatitis,
  - severe pruritus,
  - morphea,
  - scleroderma,
  - cutaneous lymphomas, or
  - other inflammatory skin conditions where the Dermatology provider has documented that treatment with home UV equipment would prevent or defer the use of systemic therapies).

Note: use of topical steroids with light therapy is standard of care for psoriasis and most forms of dermatitis; ongoing topical steroid use is not a contraindication to light therapy.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created guideline	10.2018
1.1	Minor language update per Department (C.Harrison MD)	12.2020

2.0	Update with Dr C Harrison, DME contracts/ rules being readdressed	08.2021
2.1	Routine review	04.2022
2.2	Routine review	06.2023
2.3	Updated Approved by: KPCO Utilization Management Committee	08.2023
3.0	Routine Annual Review	09.2024

Utilization Management Department
KPCO Criteria for Hospital Grade Breast Pump Use

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Hospital Grade Breast Pump Use

This guideline was developed to support clinician and utilization review teams about appropriate use of Hospital Grade Breast Pump rentals. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Hospital Grade Breast Pump Use

Rental of a Hospital Grade Breast Pump (E0604) may be considered if ALL of the following are met:

1. Mother is engaged in breast feeding.
2. A provider has documented that a hospital grade breast pump is medically necessary and that a single-use pump will not suffice: physician, CNM, Board Certified Lactation Consultant, or PA/NP, and the request is not solely due to a mother's self-report of inadequate milk production.
3. At least ONE of the following conditions exists:
    a. Baby is hospitalized and mother is not hospitalized for a period of > 1 day
    b. There is a medical need for separation of the mother and infant for a period of > 2 days
    c. Baby is pre-term defined as born before 36 weeks 6 days
    d. Baby is low birth weight, defined as < 2500gm at birth
    e. Baby has excessive weight loss at any point after birth, defined as > 10% of birth weight
    f. Pregnancy produced two or more live births (e.g. twins or higher)
    g. Baby has documented poor latch and hyperbilirubinemia as a result
    h. Baby has a congenital craniofacial abnormality such that normal nursing is difficult or impossible (ex.: ankyloglossia, cleft lip/palate, etc.)
4. The request is not to establish or re-establish lactogenesis due to mother/baby separation because of factors other than illness or hospitalization.
5. The request is for device rental; purchase of a hospital grade pump is not covered.
    a. A rental period of 60 days will be approved for ANY of the following diagnoses in the child:
        i. Prematurity, defined as birth before 32 weeks zero days EGA
        ii. Cleft lip and/or palate
    b. A rental period of 30 days will be approved for requests meeting criteria 1-4 , above.
    c. Rental renewals for 30-day periods will be considered on a case-by-case basis and are rarely medically necessary.

6. The request is not for milk storage supplies and devices, which are not covered as OTC convenience items because such items are excluded from coverage.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, derived heavily from KPMAS guideline. No prior guideline for this specific item type.	05.2021
1.1	Routine review	04.2022
1.2	Routine review – no changes made	06.2023
1.3	Routine review – no changes made	08.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Hyaluronic Acid Derivative Injections – Medicare Only

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Hyaluronic Acid Derivative Injections – Medicare Only

Criteria for Hyaluronic Acid Derivative Injections – Medicare Patients Only

Covered Indications

Intra-articular injections of hyaluronic preparations ("viscosupplementation) to the knee may be indicated when **ALL** of the following are met:

1. Documentation of knee pain which interferes with the activities of daily living such as ambulation and prolonged standing, or pain interrupting sleep, crepitus, and/or knee stiffness.
2. The clinical diagnosis is supported by radiologic evidence of osteoarthritis of the knee such as joint space narrowing, subchondral sclerosis, osteophytes and sub-chondral cysts.
3. Other diagnoses have been excluded by appropriate evaluation and management services, laboratory and imaging studies (i.e., the pain and functional disability is not considered likely to be due to a diagnosis other than osteoarthritis of the knee).
4. The patient has failed at least three months of conservative therapy. Conservative therapy is defined as ALL of the following:
    a. Nonpharmacologic therapy (such as but not limited to home exercise program, education, weight loss, physical therapy if indicated); and
    b. If not contraindicated, simple analgesics and (e.g., acetaminophen) or NSAIDS
    c. The patient has failed to respond to aspiration of the knee when effusion is present and
    d. Intra-articular corticosteroid injection therapy when intra-articular corticosteroids are not contraindicated.

A **repeat series** of hyaluronan knee injection(s) may be indicated when ALL of the following are met:

1. Documentation of knee pain which interferes with the activities of daily living such as ambulation and prolonged standing, or pain interrupting sleep, crepitus, and/or knee stiffness.
2. At least six months have elapsed since the prior series of injections
3. EITHER of these conditions is met:
    a. There is documentation of significant improvement in pain and functional capacity achieved with the prior series of injections
    b. There is significant reduction in the doses of NSAID medications taken or reduction in the number of intra-articular steroid injections to the knees during the six-month period following the injection(s).

Limitations

1. Injections for joints other than the knee are not covered.
2. Imaging for needle localization is not medically reasonable or necessary.
3. Viscosupplementation is not medically reasonable or necessary in the recovery period for any other knee surgery on the affected knee.
4. Viscosupplementation is not medically reasonable or necessary for diagnoses other than osteoarthritis

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Guideline created Medicare LCD 35427, update 5/20/2019.	08.2019
1.1	Routine review , no edits	03.2021
1.2	Re-introduced into Clinical Library after LCD 35427 was withdrawn.	7.2023
1.3	Routine annual review; no changes made per Dr. Kevin Hug, KP ortho	9.2024

SUPPORTING EVIDENCE:

Summary of Evidence

Technology Assessment Systematic Review

- Newberry et al[4] conducted a systematic review for effectiveness of hyaluronic acid in the treatment of severe degenerative joint disease (DJD) of the knee. The Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS) requested from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ), a review of the evidence that intraarticular injections of hyaluronic acid (HA) in individuals with degenerative joint disease (osteoarthritis [OA]) of the knee improve function and quality of life (QoL) and that they delay or prevent the need for total knee replacement (TKR), specifically for individuals age 65 and over. The results of the systematic review were as follows: Only one randomized controlled trial (RCT) reported on delay or avoidance of TKR as a pre-specified outcome of interest and found a non-statistically significantly longer delay of TKR compared with placebo; two RCTs reported TKR only as a secondary outcome; and 13 published observational studies reported on TKR as an outcome in HA-treated participants.

  Eighteen RCTs that enrolled participants of average age 65 or older reported on functional outcomes of intra-articular HA injection: pooled analysis of ten sham-injection placebo-controlled, assessor-blinded trials showed a standardized mean difference of -0.23 (95% CI -0.34, -0.02) significantly favoring HA at 6 months' follow-up. Durability of effect could not be assessed because of the short duration of most studies. Too few head-to-head trials were available to assess superiority of one product over another. Three RCTs that compared changes in QoL/Health-Related (HR) QoL between HA- and placebo-treated participants reported no differences between active treatment and placebo. Two recent large, good quality systematic reviews that conducted meta-

analysis of the effects of HA on pain and function (pooling 71 and 52 RCTs for the outcome of pain, respectively) showed a significant and clinically important effect of HA on both outcomes among adults of all ages, but a subgroup analysis that included only the largest double-blind placebo-controlled studies reduced the average effect of HA to less than the prespecified minimum clinically important difference. Studies of intra-articular HA reported few serious adverse events, with no statistically significant difference in the rates of serious or non-serious adverse events between HA- and placebo-treated groups.

The authors concluded that trials enrolling older participants show a small, statistically significant effect of HA on function and relatively few serious adverse events; however no studies limited participation to those 65 years or older. No conclusions can be drawn from the available literature on delay or avoidance of TKR through the use of HA. Studies that can compare large numbers of treated and untreated individuals, preferably with a randomized design, are needed to answer this question.

Evidence-Based Guidelines

- The Department of Veterans Affairs (VA) and The Department of Defense (DoD) Evidence Based Clinical Practice Guideline for Non-surgical Management of the Hip and Knee Osteoarthritis Guideline Summary[5] states there is insufficient evidence to recommend for or against the use of intra-articular hyaluronate/hylan injection in patients with osteoarthritis of the knee; however, it may be considered for patients who have not responded adequately to nonpharmacologic measures and who have an inadequate response, intolerable adverse events, or contraindications to other pharmacologic therapies.

- The National Institute for Health and Care Excellence (NICE) Clinical Guideline Osteoarthritis: care and management[6] recommendations include: do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

- The American Academy of Orthopaedic Surgeons (AAOS) Treatment of Osteoarthritis of the Knee: Evidence-Based Guideline, 2nd Edition[7], is based on a systematic review of the current scientific and clinical research. This guideline contains 15 recommendations, replaces the 2008 AAOS clinical practice guideline, and was reevaluated earlier than the 5-year recommendation of the National Guideline Clearinghouse because of methodologic concerns regarding the evidence used in the first guideline. The current guideline does not support the use of viscosupplementation for the treatment of osteoarthritis of the knee. In addition, the work group highlighted the need for better research in the treatment of knee osteoarthritis.

- Hochberg et al[8] (American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee) conditionally recommended for the initial management of patients with knee OA included acetaminophen, oral and topical NSAIDs, tramadol, and intraarticular corticosteroid injections. Intraarticular hyaluronate injections, duloxetine, and opioids were conditionally recommended in patients who had an inadequate response to initial therapy.

Published Literature

- Filardo et al[9] conducted a double-blind randomized controlled trial to evaluate the effects, in terms of pain control and functional recovery, provided by a single HA injection performed at the end of arthroscopic meniscectomy. The results showed no major adverse events were reported using HA postoperatively. A statistically significant increase in all the clinical scores was reported in both treatment groups, but no significant intergroup difference was documented at any follow-up evaluation. No difference was observed also in the objective measurements. The mean time to return to full sports activity was not different between groups, and a comparable satisfaction rate was recorded in both treatment groups. The authors concluded that early postoperative viscosupplementation did not provide significant clinical benefits after arthroscopic meniscectomy. Despite the lack of major adverse events, the administration of a single HA injection at the end of the surgical procedure is not a successful strategy to provide either faster functional recovery or symptomatic improvement after meniscectomy.

- DiMartino et al[10] conducted a double-blind, randomized controlled trial to evaluate pain control and functional recovery provided by a single injection of HA performed the day after anterior cruciate ligament (ACL) reconstruction. The results showed no severe adverse events were documented after early viscosupplementation. A significant improvement was documented in both treatment groups. Significant differences were documented in the transpatellar circumference at 60 days and in active range of motion (ROM) at 30 days postoperatively; patients who received HA had better values compared with the placebo group (P equal to .022 and .027, respectively). No statistically relevant intergroup differences were found in the clinical scores. The authors concluded that the study documented no adverse events and had some positive findings in terms of active ROM recovery and transpatellar circumference reduction. However, the early postoperative application of viscosupplementation did not lead to significant improvement in clinical scores after ACL reconstruction.

- Berkoff et al[11] conducted a review to determine the effect of ultrasound guidance on the accuracy of needle placement, clinical outcomes, and cost-effectiveness in comparison with anatomical landmark-guided intra-articular large joint injections, with particular emphasis on the knee. A total of 13 relevant studies were identified; five studied the knee, seven studied the shoulder, one used both the knee and shoulder, and none studied the hip. Ultrasound was used in seven studies; the remaining studies utilized air arthrography, fluoroscopy, magnetic resonance arthrography, or magnetic resonance imaging. Across all studies (using all imaging modalities and all joints), needle placement accuracy ranged from 63% to 100% with ultrasound and from 39% to 100% with conventional anatomical guidance. Imaging guidance improved the accuracy of intra-articular injections of the knee (96.7% versus 81.0%, P less than 0.001) and shoulder (97.3% versus 65.4%, P less than 0.001). In particular, ultrasound guidance of knee injections resulted in better accuracy than anatomical guidance (95.8% versus 77.8%, P less than 0.001), yielding an odds ratio of 6.4 (95% confidence interval 2.9-14). Ultrasound guidance notably improves injection accuracy in the target intra-articular joint space of large joints including the knee. The enhanced injection accuracy achieved with ultrasound needle guidance directly improves patient-reported clinical outcomes and cost-effectiveness.

Analysis of Evidence (Rationale for Determination)

Various polymers of hyaluronic acid have been approved and marketed as implanted prosthetic devices. Clinical practice guidelines for the treatment of knee osteoarthritis have conflicting recommendations for intra-articular hyaluronic acid treatment for knee

osteoarthritis.[12] The systematic review by the technology assessment program[4] reported a small, statistically significant effect of HA on function. Clinical studies of sodium hyaluronate and hylan G-F 20 have demonstrated that injection of these agents into the joint space of osteoarthritic knees is sometimes marginally more effective than placebo procedures in reduction of pain and improvement in functional capacity in some patients. These marginal beneficial results are more pronounced with the larger molecular weight compound hylan G-F 20. There is no data indicating that these agents reverse or retard the osteoarthritic process in the injected joints. The long-term effects of repeated injections are unknown.

Literature evaluating pain control and functional recovery of viscosupplementation performed at the end of arthroscopic meniscectomy or in the postoperative period after ACL reconstruction does not demonstrate significant clinical benefits.[9-10]

Literature suggests that fluoroscopy or ultrasound guidance may improve injection accuracy in the target intra-articular joint space of large joints including the knee. The use of other imaging procedures for viscosupplement injections has not been established as having an improvement on health outcomes.

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Utilization Management Department
KPCO Criteria for Hypoglossal Nerve Stimulation Surgery

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Hypoglossal Nerve Stimulation Surgery (Inspire®)

This guideline was developed to support clinician and utilization review teams about appropriate use of hypoglossal nerve stimulation surgery (Inspire® device). It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Hypoglossal Nerve Stimulation Surgery (Inspire®)

Hypoglossal Nerve Stimulation Surgery (e.g. Inspire® device use) may be considered if BOTH of the following are met:

1. ALL of the following qualifying criteria are met:
    a. At least 18 years of age
    b. Moderate to severe obstructive sleep apnea with AHI 15-65 with <25% central apneas
    c. Positive airway pressure (PAP) treatment failure (inability to eliminate OSA with AHI >15 despite PAP use)
    d. Inability to use PAP therapy greater than 5 nights per week for greater than 4 hours per night
2. NONE of the following disqualifying criteria are present:
    a. BMI > 35.
    b. Central + mixed apneas >25% of total AHI
    c. Any anatomical finding that would compromise the performance of the upper airway stimulation, such as complete concentric collapse of the soft palate
    d. Any condition or procedure that has comprised neurological control of the upper airway
    e. Patients who are unable or do not have the necessary assistance to operate the sleep remote
    f. Patients who are pregnant or plan to become pregnant
    g. Patients with an implantable device that may be susceptible to unintended interaction with the Inspire System.

The procedure is done as hospital, outpatient, and does not require an inpatient stay.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline by Drs. S Richey and K Pettijohn, content based on published literature and FDA approval documents for the device.	01.2021
1.1	Medicare LCD L38385 allows BMI up to 35. Point 2a updated	07.2021

1.2	Routine review Drs. S. Richey (sleep) and K. Pettijohn (HNS)	04.2022
1.3	After discussion with Dr. Richey, changed the age in (1)(a) and added the last statement regarding venue management.	06.2023
1.4	Routine maintenance, clarification GL is for Commercial only	04.2024
1.5	Routine annual review. No changes needed.	08.2024

Utilization Management Department
KPCO Criteria for Female Infertility Referrals

Sub department(s): Utilization Management QRC and Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Female Infertility Referrals

This guideline was developed to support clinician and utilization review teams about appropriate use of Female Infertility Referrals. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Female Infertility Referrals

Referral for a female patient to a fertility specialist may be considered if ALL of the following are met:

1. Patient has a fertility benefit relevant to the services being requested, including EITHER of these:
    a. Patient is being referred for services related to IUI and BOTH of these are true:
        i. Patient has IUI benefit
        ii. Patient has not exhausted her lifetime maximum limit of IUI cycles.
    b. Patient is being referred for services related to IVF and BOTH of these are true:
        i. Patient has IVF benefit
        ii. Patient has not exhausted her lifetime maximum limit of IVF cycles.

2. The patient is NOT being referred for a service excluded by the EOC, such as:
    a. Reversal of voluntary fertility,
    b. Acquisition of semen or eggs (oocytes) for a non-covered service (ex. for a patient who does not have IVF benefit),
    c. For storage of semen, eggs, or embryos, UNLESS the patient has the Fertility Preservation Benefit AND is about to undergo a medical procedure that impairs future fertility (i.e. chemotherapy, pelvic irradiation, gonadal surgery, or gender affirming treatment).
    d. Services related to Surrogacy, unless the patient has an active Kaiser plan and meets Parts 1 and 3 of this guideline.

3. A suitable initial evaluation for infertility has been completed, as shown by ANY of the following:
    a. Recurrent pregnancy loss diagnosed by an OB/GYN specialist.
    b. Patient is over age 38 and is pre-menopausal.
    c. Patient is over age 35, less than age 38, and has attempted pregnancy for more than 6 months.
    d. Patient is under age 35 and ANY of these is true:
        i. Anovulatory infertility not responsive to oral agents, including use of clomid or letrozole.
        ii. Inability to conceive after 3 cycles oral agents including use of clomid or letrozole
        iii. ANY one of these is true:

1. Diagnosis of anovulatory infertility with an inability to use home ovulation predictor kits OR
2. Failure of conception after 6 months using home ovulation predictor kits OR
3. Patients with PCOS and skipped or irregular menstrual cycles not using hormones and failure to conceive after 6 months of unprotected intercourse.

iv. Documented family history of early menopause, defined as spontaneous cessation of menstrual cycles before the age of 40.

v. Documented Tubal Factor infertility other than by a voluntary sterilization procedure, as shown by an abnormal hysterosalpingogram (HSG).

vi. Hormonal abnormality, as shown by ONE OR MORE of these:
1. Elevated FSH > 10 mIU on day 2 or 3 of cycle, or
2. Elevated estradiol > 80pg/mL, or
3. Decreased anti-Mullerian hormone <1ng/mL

vii. Patient a single ovary, or a history of ovarian surgery, chemotherapy, or pelvic radiation therapy.

e. Patient is a biological female (i.e. has functioning female reproductive anatomy) in a same-sex relationship and has the benefit for IUI and/or IVF

f. Abnormal semen analysis in the male partner, other than due to voluntary sterilization, if pregnancy is being sought through use of a male partner.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, collaboration with K.Maloney DO, RSC Ob/Gyn	03.2021
1.1	Added clarifying language on 3.c.ii, advice of Dr. Maloney; added language for same sex couples.	05.2021
1.2	Clarified age requirement 3a and removed 3.c.viii, because REI contracted providers can order lab and other testing in KP, so performing these tests prior to referral is not necessary to accomplish the goal of doing all appropriate testing in KP.	07.2021
1.3	Update language for new IVF benefits and Fertility Preservation benefits required by 2023 state laws. Reformatted section 2 to a list and clarified 3.c.iii into list form.	02.2023
1.4	Added 3(a) – Swan Davis, D.O., UMMD	08.2023
1.5	Routine review – clarification 3.e to ensure the GL for female infertility referrals applies only to persons with functioning female reproductive anatomy.	08.2024

Utilization Management Department
KPCO Criteria for Male Infertility Referrals

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Male Infertility Referrals

This guideline was developed to support clinician and utilization review teams about appropriate use of Male Infertility Referrals. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Male Infertility Referrals

Referrals to an Infertility Specialist for Male Infertility may be considered if ALL of the following are met:

1. The patient has an Infertility Benefit as part of their insurance plan.
2. A Urology evaluation has been done and no reversible causes of infertility have been found.
3. A semen analysis has been completed.
4. The patient is not seeking coverage for non-covered services, such as reversal of voluntary infertility (i.e. has had a vasectomy) or sperm retrieval services.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, Urology Input ASC Dr. J Green, and J. Dall'Era.	11.2021
1.1	Routine review by Swan Davis, D.O., UMMD	08.2023
2.0	Removed the requirement for scrotal ultrasound per KP Urology Chief	02.2024
2.1	Routine annual review. No changes needed per KP Urology Medical Director, Dr. Justin Green	08.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Injectable Calcimimetic Medications

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Injectable Calcimimetic Medications

This guideline was developed to support clinician and utilization review teams about appropriate use of Calcimimetic medication therapy. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Background

Calcitriol and vitamin D analogs are no longer routinely recommended for treatment of high PTH in CKD, due to concerns of hypercalcemia. Calcimimetics are the preferred alternative. Oral cinacalcet is the preferred agent. The available injectable medications (etelcalcetide and velcalcetide) do not have evidence demonstrating their superiority to cinacalcet. It appears that these two CAMS agents are attractive to some nephrologists because they are given in the dialysis center, thus negating the need for adherence. Available research comparing these two agents to cinacalcet does not demonstrate greater efficacy or safety for the injectable medications. In fact, GI intolerance issues seen with cinacalcet (the main drawback with the oral drug) are also seen with the injectable medications in this class.

Criteria for Injectable Calcimimetic Medications

Injectable calcimimetic therapy (etelcalcetide, velcalcetide) may be indicated if ALL of the following are met:

1. End stage renal disease (ESRD) currently on dialysis
2. Documented secondary hyperparathyroidism, demonstrated by serum PTH levels above the upper limits of the particular test.
3. Unable to take oral cinacalcet as shown by ONE OR MORE of the following:
    a. Documented allergy to cinacalcet, not documented gastrointestinal side effects
    b. Chronic liver disease, documented as Child-Pugh class B or C
4. No documented contraindication to Calcimimetic therapy, which includes ANY of the following:
    a. Primary hyperparathyroidism
    b. Documented Long QT syndrome
    c. Heart Failure stage C or D
    d. Seizure disorder requiring management with seizure medications
    e. Hypotension not responsive to calcium repletion and discontinuation of antihypertensive agents.
    f. Active GI bleed within 6 months prior to administration

References

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- CMS.gov, ESRD PPS TDAPA program, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html (accessed October 2019).

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline	10.2019
1.1	Routine review	02.2021
1.2	Routine review	03.2022
1.3	Routine review, minor changes	09.2023
1.4	Routine review	09.2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria: Intraocular Lens Following Cataract Extraction

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

Medicare Members

CMS Coverage Manual	(none)
National Coverage Determinations (NCD)	80.12 Intraocular Lens
Local Coverage Determinations (LCD)	(none)
Other Pertinent Documents	Transmittal TN914 and A56615

Non-Medicare Members

Accommodative Intraocular Lens

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Multifocal Intraocular Lens

Multifocal intraocular lenses will not be covered. Standard monofocal intraocular lenses are covered following cataract surgery. The patient may elect to pay for the multifocal lens.

Toric Intraocular Lens

Toric intraocular lenses to correct astigmatism are not covered. The purposes of these lenses are to reduce dependence on glasses. Improved vision with glasses is the purpose of standard cataract surgery, the additional benefit of improved vision without glasses is not a covered service.

If requesting review for this service, please send the following documentation:

• Last 6 months of clinical notes from requesting provider &/or specialist

Applicable Codes

Codes not considered medically necessary:

V2787	Astigmatism correcting function of IOL
V2788	Presbyopia correcting function of IOL

History of Changes

Version Number	Description of Changes	Effective Date
1.0	Development of guideline based on KPWA guideline of the same name. Dr. G. Bang, SMD, advising. Passed 8/26 UM Committee.	10/1/2024

UTILIZATION MANAGEMENT
KPCO Criteria for Intraoperative Neuromonitoring

Sub department(s): Utilization Management MD	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Intraoperative Neuromonitoring

Criteria for Intraoperative Neuromonitoring

Intra-operative neurophysiological testing (aka "intraoperative neuromonitoring," (IONM)) may be necessary when ALL of the following are met:

1. Coding requirements are met, as shown by BOTH of the following:
    a. At least one of the following codes appears on IONM request. Codes 95940 and 95941 may not be billed on the same request:

Code	Explanation
95940	IONM, one case at a time, within the OR (per 15 min)
95941	IONM, outside the OR or more than one case within the OR (per hour)
G0453	IONM, outside the OR, per patient (per 15 min)

    b. Can approve the base code, if medical necessity for IONM is met, even if the medical necessity is not met for any of the "group" codes noted in the subsequent sections.

    c. The correct modifiers are used *(Of note, the codes in number 1.a., above, will not have a modifier, but all the other IONM cpt codes should have the 26 modifier)*:
        i. Modifier -26 Professional fees: benefit covers only professional fees, which are properly billed with -26 modifier.
        ii. Modifier -TC Technical fees: benefit does not cover technical fees, benefit denial. These are properly billed to the facility.
        iii. No Modifier, Global Fee: if the IONM services are billed with no modifier it is a request for the Global Fee, which includes both Professional and Technical components. Because the Technical component isn't a covered benefit, IONM codes billed for the Global Fee are a benefit denial.

2. The request is for a surgical procedure for which IONM has demonstrated benefit, including ONE OR MORE of the following:

    a. **Group 1** Codes:
        i. Vascular surgery where there is risk of cerebral or spinal cord ischemia, including ANY of these:
            1. Surgery of the aortic arch or its branch vessels,
            2. Thoracic aortic surgery

3. Distal aortic procedures, where there is risk of ischemia to spinal cord

ii. Spinal surgery, including ANY of these:
    1. Correction of scoliosis
    2. Correction of deformity of spinal cord involving traction of the cord
    3. Protection of spinal cord where work is performed in close proximity to cord as in the placement or removal of old hardware or where there have been numerous interventions
    4. Spinal instrumentation requiring pedicle screws or distraction
    5. Decompressive procedures on the spinal cord or cauda equina carried out for myelopathy or claudication where there is documented risk to function of the spinal cord or spinal nerves
    6. Spinal cord tumors
    7. Spinal fractures with the risk of cord compression
    8. Surgery for arteriovenous malformation of spinal cord
    9. Surgery as a result of traumatic injury to spinal cord
iii. Peripheral vascular or neurological procedures, including ANY of these:
    1. Neuromas of peripheral nerves of brachial plexus when there is documented risk to major sensory or motor nerves
    2. Embolization of bronchial artery AVMs or tumors
iv. Any procedure for which there is circulatory arrest with hypothermia (does not include surgeries performed under circulatory bypass [e.g., CABG, ventricular aneurysms])
v. Orthopedic procedures, including ANY of these:
    1. Leg lengthening procedures, where there is traction on sciatic nerve or other nerve trunks

Group 1

95925	SSEP upper limbs - may not appear with 95926 or 95938. **Not indicated for surgery below T1 spinal level.**
95926	SSEP lower limbs - may not appear with 95925 or 95938
95938	SSEP upper and lower limbs - may not appear with 95925 or 95926. **Not indicated for surgery below T1 spinal level.**
95928	MEP upper limbs - may not appear with 95929 or 95939. **Not indicated for surgery below T1 spinal level.**
95929	MEP lower limbs - may not appear with 95928 or 95939
95939	MEP upper and lower limbs - may not appear with 95928 or 95929. **Not indicated for surgery below T1 spinal level.**
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
95927	SSEP trunk or head
92585	Auditory evoked potentials comprehensive
92586	Auditory evoked potentials limited

Group 1 and Group 2 codes

vi. Cranial surgery, including ANY of these:
    1. Resection of epileptogenic brain tissue or tumor
    2. Resection of brain tissue close to the primary motor cortex and requiring brain mapping
    3. Surgery or embolization for intracranial AV malformations
    4. Cerebral vascular aneurysms
    5. Surgery for the correction of movement disorders, including basal ganglia procedures.
    6. Deep brain stimulation procedures
    7. Surgery as a result of traumatic injury to the brain

vii. Carotid artery procedures
    1. Carotid artery surgery
    2. Arteriography during which there is a test occlusion of the carotid artery

Group 1

95925	SSEP upper limbs - may not appear with 95926 or 95938. **Not indicated for surgery below T1 spinal level.**
95926	SSEP lower limbs - may not appear with 95925 or 95938
95938	SSEP **upper and lower limbs** - may not appear with 95925 or 95926. **Not indicated for surgery below T1 spinal level.**
95928	MEP **upper limbs** - may not appear with 95929 or 95939. **Not indicated for surgery below T1 spinal level.**
95929	MEP **lower limbs** - may not appear with 95928 or 95939
95939	MEP **upper and lower limbs** - may not appear with 95928 or 95929. **Not indicated for surgery below T1 spinal level.**
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
95927	SSEP trunk or head
92585	Auditory evoked potentials comprehensive
92586	Auditory evoked potentials limited

Group 2

95813	Electroencephalogram (EEG) extended monitoring >1h
95822	Electroencephalogram (EEG) in coma or sleep only
95955	Electroencephalogram (EEG) non-intracranial surgery

b. **Group 1**, **Group 2,** and **Group 3** codes:
    i. Surgery implicating cranial nerves, including ANY of these:
        1. Resection of tumors involving the cranial nerves
        2. Cavernous sinus tumors
        3. Microvascular decompression of cranial nerves
        4. Skull base surgery in the vicinity of the cranial nerves
        5. Surgeries of the foramen magnum
        6. Oval or round window graft
        7. Endolymphatic shunt for Meniere's disease
        8. Vestibular section for vertigo
        9. Cochlear implant surgery
    ii. Surgery for the correction of movement disorders, interpreted to include dorsal rhizotomy

Group 1

95925	SSEP upper limbs - may not appear with 95926 or 95938. **Not indicated for surgery below T1 spinal level.**
95926	SSEP lower limbs - may not appear with 95925 or 95938
95938	SSEP **upper and lower limbs** - may not appear with 95925 or 95926. **Not indicated for surgery below T1 spinal level.**
95928	MEP **upper limbs** - may not appear with 95929 or 95939. **Not indicated for surgery below T1 spinal level.**
95929	MEP **lower limbs** - may not appear with 95928 or 95939
95939	MEP **upper and lower limbs** - may not appear with 95928 or 95929. **Not indicated for surgery below T1 spinal level.**
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
95927	SSEP trunk or head
92585	Auditory evoked potentials comprehensive
92586	Auditory evoked potentials limited

Group 2

95813	Electroencephalogram (EEG) extended monitoring >1h
95822	Electroencephalogram (EEG) in coma or sleep only
95955	Electroencephalogram (EEG) non-intracranial surgery

Group 3

95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95885	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited
95886	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (List separately in addition to code for primary procedure)
95887	Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study
95900	Nerve conduction, amplitude and latency/velocity study, each nerve; motor, without F-wave study

c. **Group 4** codes:
    i. Thyroid procedures where ANY of the following are documented for CPT codes 60220, 60240, 60254, 20620:
        1. High-risk total removal of a complete lobe of the thyroid,
        2. Removal of the entire gland, or
        3. Procedure involves re-entry (re-operation) to a prior surgical field where scar tissue obscures the visual path of the recurrent laryngeal nerve

Group 4

95865	Needle electromyography; larynx
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95872	Needle electromyography, other
95955	Electroencephalogram (EEG) during non-intracranial surgery

Group 5 codes are considered experimental and investigational and are not covered.

Group 5

95903	Nerve conduction, amplitude and latency/velocity study, each nerve; motor, with F-wave study
95904	Nerve conduction, amplitude and latency/velocity study, each nerve; sensory
95905	Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report
95907, 95908, 95909, 95910, 95911, 95912, 95913	Nerve conduction studies 1-2, 3-4, 5-6, 7-8, 9-10, 11-12, 13+
95930	Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method
95999	Unlisted neurological or neuromuscular diagnostic procedure
95829	Electrocorticogram
95921	testing autonomic funciton (vagal, adrenergic, sudomotor, tilt study)
95922	
95923	
95924	
95933	oribicularis oculi / blink reflex testing
95961	functional brain mapping, in-person attendance
95962	functional brain mapping, in-person attendance

Full Code Descriptions:

Code	Explanation
95940	IONM, one case at a time, within the OR, per 15 min
95941	IONM, outside the OR or more than one case from within the OR, per hour
G0453	IONM, outside the OR, per patient, each 15 min

Group 1

95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in **upper limbs** - may not appear with 95926 or 95938. **Not indicated for surgery below T1 spinal level.**
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in l**ower limbs** - may not appear with 95925 or 95938
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in **upper and lower limbs** - may not appear with 95925 or 95926. **Not indicated for surgery below T1 spinal level.**
95928	Central motor evoked potential study (transcranial motor stimulation); **upper limbs** - may not appear with 95929 or 95939. **Not indicated for surgery below T1 spinal level.**
95929	Central motor evoked potential study (transcranial motor stimulation); **lower limbs** - may not appear with 95928 or 95939
95939	Central motor evoked potential study (transcranial motor stimulation); in **upper and lower limbs** - may not appear with 95928 or 95929. **Not indicated for surgery below T1 spinal level.**
51792	Stimulus evoked response (eg, measurement of bulbocavernosus reflex latency time)
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
92585	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive - may not appear with 92586
92586	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited - may not appear with 92585

Group 2

95813	Electroencephalogram (EEG) extended monitoring; greater than 1 hour
95822	Electroencephalogram (EEG); recording in coma or sleep only
95955	Electroencephalogram (EEG) during nonintracranial surgery

Group 3

95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95885	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited
95886	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (List separately in addition to code for primary procedure)
95887	Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study
95900	Nerve conduction, amplitude and latency/velocity study, each nerve; motor, without F-wave study

Group 4

95865	Needle electromyography; larynx
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95872	Needle electromyography using single fiber electrode, with quantitative measurement of jitter, blocking and/or fiber density, any/all sites of each muscle studied
95955	Electroencephalogram (EEG) during non-intracranial surgery

History and Background

Intraoperative neurophysiological testing may be used to identify/prevent complications during surgery on the nervous system, its blood supply, or adjacent tissue. Monitoring can identify new neurologic impairment, identify or separate nervous system structures (e.g., around or in a tumor) and can demonstrate which tracts or nerves are still functional. Intraoperative neurophysiological testing may provide relative reassurance to the surgeon that no identifiable complication has been detected up to a certain point, allowing the surgeon to proceed further and provide a more thorough or careful surgical intervention than would have been provided in the absence of monitoring. Monitoring, if used to assess sensory or motor pathways, should assess the appropriate sensory or motor pathways. Incorrect pathway monitoring could miss detection of neural compromise and has been shown to have resulted in adverse outcomes.

Criteria

- Medicare LCD 35003, Intraoperative Neurophysiological Testing (update 11/14/2019, verified 10/13/2020, 07/07/2022)
- Medicare LCA A56722, Billing and Coding: Intraoperative Neurophysiological Testing (update 07/25/2019)

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Medicare-specific GL created; L35003 Novitas	07.2019
1.1	Broaden GL to Medicare and Commercial both; verified current version is 7/25/19 update	10.2019
2.0	Code revision and visual improvements	11.2019
2.1	Code tables changed from .jpg to Excel tables for easier formatting.	01.2020
2.2	Re-ordered tables to include directly in the relevant sections	05.2020
2.3	Clarified Group 4 codes and qualifying surgeries.	10.2020
3.0	Full re-evaluation of guideline and literature survey. MCG: no result outside of L353003, verified consistency. Hayes: mostly D2. Other KP regions: consistent, except thyroid IONM is not required by other regions' MACs. Other insurers: no major changes to guideline, which is broadly consistent with Anthem CG-SURG-104 (accessed 7/7/22) as a representative example.	07.2022
3.1	Added 95867 to group 3, often used in cochlear surgery; HNS leadership approved.	08.2022
3.2	Added 1.b., added italicized statement in 1.c.	06.2023
3.3	Clarification: for use with Commercial only.	4.2024
3.4	Routine annual review. No changes needed	8.2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria:

Ketamine for the treatment of depression or other psychiatric disorders.

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

Medicare Members

CMS Coverage Manual	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Other Pertinent Documents	None

Non-Medicare Members

Ketamine (intranasal, intravenous, or subcutaneous) for depression or other psychiatric disorders is considered **experimental and investigational** because its clinical value has not been established. Non-covered diagnoses include but are not limited to:

- Depression (any form)
- Generalized anxiety disorder and social anxiety disorders
- Substance Use Disorder
- Suicidal Ideation.

Note: evaluations to determine appropriateness for ketamine treatment are not covered, because services incident-to non-covered services are also not covered.

Applicable Codes

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® or HCPCS Codes	Description
90792	Psychiatric diagnostic evaluation with medical services
J3490	Unclassified drugs
Commonly submitted with CPT code(s) 96365, 96366, 96367, or 96368	
ICD-10 Codes	**Description**
F01-F09	Mental disorders due to known physiological conditions
F10-F19	Mental and behavioral disorders due to psychoactive substance use
F20-F29	Schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders
F30-F39	Mood [affective] disorders
F40-F48	Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders
F50-F59	Behavioral syndromes associated with physiological disturbances and physical factors
F60-F69	Disorders of adult personality and behavior
F70-F79	Intellectual disabilities
F80-F89	Pervasive and specific developmental disorders
F90-F98	Behavioral and emotional disorders with onset usually occurring in childhood and adolescence
F99-F99	Unspecified mental disorder
T14.91XA	Suicidal behavior with attempted self-injury
R45.89	Suicidal behavior without attempted self-injury
T65.92XA	Suicidal deliberate poisoning
R45.851	Suicidal ideation
R45.851	Suicidal ideations
R45.851	Suicidal intent
T50.902A	Suicidal overdose
T50.902A	Suicidal overdose, initial encounter
T50.902S	Suicidal overdose, sequela
T50.902D	Suicidal overdose, subsequent encounter
R45.89	Suicidal risk
R45.851	Suicidal thoughts
R45.851	Feeling suicidal
T40.602A	Narcosis due to narcotic, purposeful, non-suicidal
Z71.1	Concern about becoming suicidal without diagnosis
F32.A, R45.851	Depression with suicidal ideation
Z91.52	History of non-suicidal self-harm
Z91.51	History of suicidal behavior

***Note: Codes may not be all inclusive. Deleted codes and codes not in effect at the time of service may not be covered.**

History of Changes

Version Number	Description of Changes	Effective Date
1.0	Guideline creation – KPWA related guideline as source.	09.2024

Related Clinical Evidence

Ketamine Infusion for Treatment-Resistant Bipolar Depression

Conclusion - D2

A small body of very low-quality evidence found that ketamine infusion rapidly reduces symptoms of severe bipolar depression. Although the antidepressant effects appear to last for only a few days, this can be clinically significant if it improves the mood of severely depressed, potentially suicidal patients. In all of the studies, only a single dose of ketamine was administered; the safety and effectiveness of repeated administration of ketamine for treatment of bipolar depression is unknown. The evidence suggests that ketamine is reasonably safe. Additional large, well-designed studies with adequate follow-up are needed to evaluate the long-term effects of prolonged ketamine treatment.

Insights

- Ketamine is administered by infusion because it does not have good bioavailability via alternative routes, such as oral or intramuscular injection.
- The low oral bioavailability and potential for abuse makes ketamine an unlikely first- or second-line therapy for bipolar depression.
- Persons with bipolar disorder are more apt to seek medical attention when they are depressed; therefore, a careful medical history must be obtained to avoid misdiagnosis of the patient's disorder as major depression.
- None of the reviewed payers had policies available for the use of ketamine to treat bipolar depression.

Ketamine as Primary Therapy for Treatment-Resistant Unipolar Depression Or Posttraumatic Stress Disorder

Conclusion- C (For ketamine as a treatment for treatment-resistant unipolar depression)

D2 (For ketamine as a treatment for posttraumatic stress disorder (PTSD).

A moderate-size body of low-quality evidence has consistently found that ketamine reduces symptoms of severe treatment-resistant unipolar depression, symptoms of PTSD, or suicidal ideation at short-term follow-up of 1 to 3 days posttreatment; however, the findings at longer-term follow-up of 1 to 4 weeks are mixed. The majority of the studies administered only a single dose of ketamine; the safety and effectiveness of repeated administration of ketamine for treatment of depression or PTSD is unknown. The evidence suggests that ketamine is reasonably safe if complications are properly managed. Additional large, well-designed studies with adequate follow-up are needed to evaluate the long-term effects of prolonged ketamine treatment, to assess simplified ketamine administration via intranasal or

subcutaneous routes, to determine the efficacy and safety of ketamine for PTSD treatment, and to evaluate the efficacy and safety of ketamine relative to ECT for unipolar depression.

Insights

- The low oral bioavailability and potential for abuse makes ketamine an unlikely first- or second-line therapy for treatment-resistant unipolar depression or PTSD.
- The reviewed studies found that ketamine is consistently beneficial for 24 hours posttreatment; however, the durability of results at 1 to 4 weeks posttreatment are mixed. Thus, it is unclear whether ketamine provides durable relief of depression or PTSD symptoms.
- As the beneficial effects of ketamine may be limited to 24 hours posttreatment, it is important to establish the safety and effectiveness of repeated administration of ketamine. There is currently a paucity of studies investigating repeated administration of ketamine for unipolar depression or PTSD.
- Several representative payer organizations do not have coverage policies for ketamine monotherapy for unipolar depression or PTSD.

Utilization Management Department
KPCO Criteria for Left Atrial Appendage Closure - Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Left Atrial Appendage Closure - Commercial

This guideline was developed to support clinician and utilization review teams about appropriate use of Left Atrial Appendage Closure procedures. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Left Atrial Appendage Closure

Hospital Outpatient Status for Left Atrial Appendage Closure (LAAC, Watchman®, et al) may be considered if ALL of the following are met:

- Nonvalvular persistent or paroxysmal atrial fibrillation[A]
- Elevated risk of embolic stroke (eg, CHA2DS2-VASc score of 2 or more in males and 3 or more in females, ATRIA score of 6 or more)
- Medical management (anticoagulation) not preferred due to **1 or more** of the following:
    - Thromboembolism while on oral anticoagulant (ie, while on therapeutic dosage, or INR in therapeutic range)
    - Elevated risk of bleeding on oral anticoagulant (eg, HAS-BLED score of 3 or more)
    - Other contraindication to long-term anticoagulation
    - Patient unable or unwilling to use long-term anticoagulation.
- Patient does not have an indication for Inpatient status based on general admission criteria as outlined by MCG guidelines.
    - If criteria for Inpatient status are met, procedure may be approved under Inpatient.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline. Based on MCG M333.	8.2023
1.1	Routine maintenance. Clarify for Commercial only	04.2024

RESOURCE STEWARDSHIP
KPCO Criteria for LINX Magnetic Sphincter Augmentation

Sub department(s): Utilization Management MD	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for LINX Magnetic Sphincter Augmentation

Criteria for LINX Magnetic Sphincter Augmentation

Background

The LINX (magnetic sphincter augmentation) procedure is an alternative to fundoplication that entails a minimally invasive laparoscopic implantation of a small device made of interlinked titanium beads with magnetic cores, which prevents reflux by augmenting the esophageal sphincter's barrier function

LINX Magnetic Sphincter Augmentation may be indicated when **ALL** the following are met:

1) Patient meets **ALL** the following criteria:
   a) Age > 18
   b) Gastroesophageal reflux disease (GERD) for at least 6 months, with pathologic confirmation of reflux on preoperative testing
   c) Persistent symptoms despite daily Proton Pump Inhibitor (PPI) use
   d) BMI <35
   e) No documented metal allergy
   f) No esophageal motility disorder.

2) Sufficient pre-operative testing has been done to include **ALL** the following:
   a) Barium swallow study – The presence of any strictures of motility concern is a contraindication to the LINX procedure.
   b) Esophagogastroduodenoscopy (EGD) - The presence of any masses concerning for cancer or narrowing at the gastroesophageal junction concerning for achalasia are contraindications for the LINX procedure. The presence of any esophagitis/Barretts esophagus is not an exclusion to the LINX procedure.
   c) Esophageal pH monitoring - Confirmation of pathologic reflux on esophageal pH monitoring is only needed for patients with grade A or B reflux or a small hiatal/paraesophageal hernia. The pH monitoring test is not medically necessary if the patient has grade C or D reflux (severe), OR Barretts esophagus on EGD, OR large hiatal/paraesophageal hernia.
   d) Esophageal manometry - Sufficient esophageal strength must be demonstrated preoperatively by esophageal motility study, especially if there has been previous esophageal surgery. The results of the study should be in the normal range. If the motility test results are marginally outside the normal range, the treating physician must document the risk discussion regarding possible post-operative dysphagia if the procedures is completed.

3) *Note: prior sleeve gastrectomy or Roux-en-Y Gastric Bypass **IS** considered a contraindication to the Linx procedure. All bariatric patients with uncontrolled gastrointestinal acid reflux, should consult with bariatric surgery to ensure they are losing weight appropriately, ensure the post bariatric anatomy is correct and does not need a revision procedure, and to see if the sleeve gastrectomy should be converted to a gastric bypass (if applicable).*

Resources and Supporting Evidence

- KP SoCal IRB inclusion criteria, Dr Umer Chaudry, email communication 10/1/2019.
- Up to Date: "Magnetic Sphincter Augmentation" [https://www.uptodate.com/contents/magneticsphincter-augmentationmsa?search=linx&source=search_result&selectedTitle=2%7E2&usage_type=default&display_rank=2]
- Up to Date: "Surgical treatment of gastroesophageal reflux in adults" [https://www.uptodate.com/contents/surgical-treatment-of-gastroesophageal-reflux-inadults?search=linx&source=search_result&selectedTitle=1%7E2&usage_type=default&display_rank=1]

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of GL using SCPMG research outcomes criteria	10.2019
2.0	Update with input from Dr D. Pham, General Surgery and LINX surgeon; approval by ASC.	07.2021
3.0	Changes made per discussion with Dr. Pham, Linx surgeon: deleted brand name, deleted redundant things in section (1), included the parameters for inclusion/exclusion criteria in (2) (a-d), added (2)(a) as a preoperative requirement, deleted the word "not" in section (3) because the bariatric surgeries listed ARE a contraindication + added the clarifying directions after the first sentence.	06.2023
3.1	Supporting evidence added from UpToDate	04.2024
3.2	Routine annual review. No changes needed	08.2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria: KPCO Criteria for Treatment of Lipedema

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

Medicare Members

CMS Coverage Manual	*None*
National Coverage Determinations (NCD)	*None*
Local Coverage Determinations (LCD)	*None*
Other Pertinent Documents	*None*

- *Surgical treatment for this condition is not covered by Medicare.*

Non-Medicare Members

Criteria for Treatment of Lipedema

Liposuction (or related procedure) for treatment of Lipedema may be considered if ALL of the following are met:

1. There is a physician diagnosis of lipedema, determined by ALL of the following:
    a. Bilateral, symmetrical, fatty tissue hypertrophy of the limbs sparing hands and feet with disproportionate fat distribution (i.e. notation of top-to-bottom asymmetry)
    b. Marked or unusual tendency to bruising and/or hematoma formation, and
    c. Limb circumference that does not meaningfully change with weight reduction, and
    d. Pain to touch disproportionate to the amount of pressure applied, and
    e. Negative Stemmer sign (inability to pinch the tissue in affected areas).
2. BMI is less than 35.0 (patient is not morbidly obese) and the time of the proposed surgical procedure.
3. The patient has completed at least 180 days of optimal medical management, including all of the following:
    a. Weight loss through calorie restriction and an adequate trial of covered medications,
    b. Compression garments, fitted by a qualified Physical Therapist, and
    c. Regular use of lymphatic drainage techniques (manual or pneumatic assisted).
4. There is a documented complication as a direct result of lipedema, determined by EITHER of the following:
    a. Meaningful functional deficits such as difficulty ambulating or performing other activities of daily living, or
    b. Severe pain, maceration, recurrent skin infections, or demonstrated venous insufficiency that are BOTH
        i. Not improved with nonoperative management, and
        ii. Significant enough to warrant surgical intervention.
5. Surgical intervention is reasonably expected to improve the complication(s) listed in point 4,

6. Photographic documentation in the record is consistent with known and accepted patterns of lipedema, i.e. is not compatible with patterns of simple obesity, lymphedema, chronic venous insufficiency, or another recognized diagnosis,
7. The request is for an Ambulatory Surgical Center venue, and
8. The surgical plan indicates a maximum of 5 liters of material is to be removed.
9. The patient has not had more than three (3) surgical procedures lifetime total.
    a. Lifetime max: 3 procedures of no mor than 5 liters of material each.
10. The request does NOT include an experimental, investigational, or unproven procedure, which are excluded from coverage:
    a. Lymphatic physiological microsurgical procedures, including but not limited to bypass, lymphatico-venous anastomosis, lymphatic-capsular anastomosis, lympho-venous transplantation.
    b. MITESE: minimally invasive tissue excision with possible redundant skin excision.
    c. Tissue Transfer, such as omental or mesenteric flap
    d. Lymphatic reconstruction
    e. Reductive radio-ablative techniques
    f. Extracorporeal shock wave therapies (EST)
    g. Preventive lymphatic physiologic microsurgery of any kind
    h. Reverse lymphatic mapping, because this is used to prepare for non-covered procedures.

Applicable Codes

CPT/HCPCS	Description
15876, 15877, 15878, 15879,	Suction assisted lipectomy.

History of Changes

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline: Hayes, ECRI, INTC, published payer guidelines. M. Kiehn MD (Plastic Surgery) contributing.	2.2024
1.1	Added 7 & 8 based on email conversation with Dr Kiehn	6.2024
1.2	Changed BMI cutoff to less than 35.0 per request of the department, through Dr. Kiehn.	6.2024
1.3	Final version approved by UM Committee vote	11.2024

Supporting Materials

MAS:

Table 1. Stages of Lipedema by Dr. Wilfried Schmeller and Dr. Karen Herbst [1].

Stages of Lipedema	Description
Stage 1	▪ Even smooth skin surface with enlarged subcutaneous fat tissue ▪ Fat buildup around pelvis, buttocks, and hips. ▪ Fat buildup from buttocks to knees, with folds of fat around the inner side of the knee. ▪ Fat buildup from buttocks to ankles
Stage 2	▪ Uneven skin pattern with the development of nodular elevations or mass-like appearance and indentations of subcutaneous fat, lipomas and/or angiolipomas ▪ Fat buildup around pelvis, buttocks, and hips. ▪ Fat buildup from buttocks to knees, with folds of fat around the inner side of the knee ▪ Fat buildup from buttocks to ankles.
Stage 3	▪ Large deforming growths of nodular fat or hanging flaps of the thighs and around the knees causing severe contour deformity of the thighs and around the knee ▪ Large extrusions of fat tissue cause buildup from buttocks to knees, with folds of fat around the inner side of the knee. ▪ Large extrusions of fat tissue causing buildup from buttocks to ankles
Stage 4	▪ Development of lipolymphedema where both lipedema and lymphedema are present in the body. This is characterized by large overhangs of tissue, dysfunctional lymphatics, and large extrusion of fat tissue on legs with progression to lipolymphedema

Lymphology 53(1), p.3-19.

[2] Herbst K. L. (2012). Rare adipose disorders (RADs) masquerading as obesity. *Acta pharmacologica Sinica*, *33*(2), 155–172.

Market Scan:

- Aetna: cosmetic
- Cigna: experimental / unproven
- United: Liposuction for Lipedema – Commercial and Individual Exchange Medical Policy (uhcprovider.com). substantially similar to the above.
- Anthem Blue Cross:
    - Significant physical functional impairment in ADL or recurrent cellulitis

- Liposuction or lipectomy is reasonably expected to improve function
- Not responded to at least 3 months of optimal medical management, and
- Compression and continued treatment postoperatively.

Utilization Management Department
KPCO Criteria for Referrals to Medical Genetics for Hypermoblity Syndromes – Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 06.2024 Next Review: 06.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Referrals to Medical Genetics for Hypermobility Syndromes

This guideline was developed to support clinician and utilization review teams about appropriate use of Referrals to Medical Genetics for Hypermobility Syndromes. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Referrals to Medical Genetics for Hypermobility Syndromes

Referrals to Medical Genetics for Hypermobility Syndromes may be considered if ANY of the following are met:

1. History of any of the following in the patient or close relatives:
    a. Spontaneous or easily induced skin cuts or tears
    b. Spontaneous wound dehiscence
    c. Recurrent or incisional hernias
    d. Sutures tearing through tissue and failing to hold
    e. Thin, translucent skin
    f. Atrophic ("cigarette paper") scars (NOT keloid scars); note, mildly atrophic scars can be seen even in normal individuals especially in areas subject to physical stress such as extensor surfaces and the abdominal wall
2. Spontaneous or easily induced tears or ruptures of intestines, uterus, or other internal organs
3. Aneurysm, artery dissection or rupture
4. Spontaneous pneumothorax
5. Scoliosis requiring surgical intervention
6. History of club foot in infancy that required treatment (serial casting and/or surgery)
7. Dislocated lens, atraumatic retinal detachment, spontaneous globe rupture, keratoconus
8. Dentinogenesis imperfecta
9. Cleft palate or bifid uvula
10. Confirmed family history or abnormal genetic lab result for a serious connective tissue disorder such as Marfan syndrome, Classic or vascular EDS, or Loeys-Dietz syndrome
11. Clinically apparent hypermobility plus another major medical issue such as epilepsy, significant developmental delays, or intellectual disability.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date

1.0	Creation of guideline based on KPWA guideline and recommendations from Dr Yuen, Medical Genetics, KPWA	4.2024
1.1	Update and clarification regarding point 11 with Dr. A Yuen.	6.2024
1.2	Typo correction	6.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Neuropsychological Testing

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Neuropsychological Testing for Commercial Members

This guideline was developed to support clinician and utilization review teams about appropriate use of Neuropsychological Testing. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Neuropsychological Testing

Neuropsychological Testing may be indicated when ALL of the following are met:

- Neuropsychological testing is needed due to cognitive or behavioral impairment as indicated by ALL of the following:
  - Testing is appropriate based on EITHER of the following:
    - Preoperative testing for implantation of a medical device into the brain, such as Deep Brain Stimulators for movement disorders and the like, OR
    - Patient's cognitive deficits, mental status abnormality, behavioral change, or memory loss symptoms require quantification, monitoring of change, differentiation of cause (eg, organic cognitive vs psychiatric disease), or confirmation of diagnosis
  - Testing regarding patient's abnormality is appropriate based on suspected or known diagnosis of ONE OR MORE of the following:
    - Cerebral dysfunction from toxic exposure
    - Cerebral mass
    - Cerebrovascular disease (eg, stroke)
    - Dementia (eg, Alzheimer disease, vascular dementia, Lewy body dementia, frontotemporal dementia) or other cognitive impairment and evaluation is needed when the diagnosis or severity cannot be determined by other means.
    - Epilepsy, when the order is placed by a Neurologist or Psychiatrist
    - Huntington disease that is either prodromal or active disease
    - Hydrocephalus
    - Infection-associated cognitive disorder (eg, HIV, Lyme disease, herpes encephalitis) with need for evaluation of significant cognitive deterioration to determine extent of organic cause and direct therapy
    - Multiple sclerosis
    - Parkinson disease
    - Primary progressive aphasia

        - Toxic effects of specific cancer treatment (eg, intrathecal methotrexate, cranial irradiation)
        - Traumatic or anoxic brain injury
        - Other diagnosis with strong evidence of, or known high risk for cognitive impairment for which test results will help provide guidance regarding specific patient care needs

- Situation and expectations are appropriate for neuropsychological testing as indicated by ALL of the following:
    - Information achieved by neuropsychological testing is not attainable through routine medical, neurologic, or psychological assessment.
    - Results of proposed neuropsychological testing are judged likely to affect care or treatment of patient (eg, contribute substantially to decision of need for, design of, or modification to rehabilitative or habilitative needs or treatment plan; to assess whether to proceed with medical or surgical procedure or complex treatment regimen; or to evaluate potential adverse effects on cognitive function of medications or therapies).
    - Neuropsychological testing is to be administered by provider whose qualifications are appropriate to proposed assessment.
    - Patient is able to participate as needed such that proposed testing is likely to be feasible (eg, mental status, intellectual or cognitive abilities, language skills, or developmental level are appropriate to proposed testing.)
    - Testing addresses comorbid medical, psychiatric, and substance use disorders, and includes coordination of care with other providers, as appropriate.
    - Patient is not engaged in active substance use, in withdrawal, or in recovery from recent chronic use
    - Testing engages family, caregivers, and other people impacted by and in position to affect patient behavior, as appropriate.
    - Time for administration, scoring, interpretation (ie, number of minutes/hours), and time spent preparing report and explaining results to patient reflects recognized norms for evaluation being completed (eg, **8 hours or fewer**).
    - Frequency of testing evaluation reflects recognized norms for evaluation being completed (eg, 1 initial testing evaluation, followed by no more than 1 additional re-testing evaluation within a 12-month period)

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline	10.2018
1.1	Routine review.	02.2021
1.2	Minor wording edits	08.2023
1.3	Approved by: KPCO Utilization Management Committee was added	08.2023
1.4	Annual review	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Neuropsychological Testing for Children

Sub department(s): Utilization Management MD	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Neuropsychological Testing for Children.

This guideline was developed to support clinician and utilization review teams about appropriate use of Neuropsychological Testing for Children. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Neuropsychological Testing for Children.

A child < 18 years old MAY qualify for neuropsychological testing if ANY of the following are met:

- Anoxic brain injury (1)
- Bone marrow/transplant patients: pre- and post-transplant
- Brain surgery candidates, prior to surgery and 9-12 months after surgery
- Brain tumor
- Concussive syndrome/multiple concussions with symptoms (1)
- Congenital brain abnormalities
- Congenital Diaphragmatic Hernia requiring ECMO
- Cyanotic heart disease, Complex heart disease requiring open heart surgery during infant period, Heart transplant patients (pre and post-transplant)
- Cystic fibrosis with behavioral hypoxia
- Diabetes with documented episodes of DKA or hypoglycemia
- Genetic disorders with known neuropsychological sequelae, e.g., Neurofibromatosis, Sex Chromosome Disorders (3), Tuberous Sclerosis, Turners, Williams, etc
- Huntington's Chorea
- Hydrocephalus (including children who have required shunts, Spina Bifida)
- Institutionalization or care in a large congregate care facility (eg Orphanage) in the first three years of life for a time period greater than 6 months (2)
- Inherited metabolic disorders (including PKU, galactosemia, etc.)
- Leukemia (ALL, AML)
- Lupus
- Multiple sclerosis
- Muscle disease with known associated neuropsychological dysfunction e.g. muscular dystrophy, merosin deficiency, movement disorders, ataxia-telangiectasia, etc.
- Neurological diagnoses which have resulted in change in function, e.g., epilepsy
- Other diagnosis with strong evidence of, or known high-risk for cognitive impairment (2)
- PANDAS/PANS (2)
- Pre/Perinatal infection with high risk of developmental/cognitive impairment (eg symptomatic congenital CMV, Zika with microcephaly, Neonatal HIV)
- Prematurity, as shown by ANY of the following: (2)
  - < 28 weeks gestation (extremely preterm infant)
  - VLBW weight < 1500gm (<3lb 4oz)

        - 28-32 weeks (very preterm infant) with low APGAR (<3) or broad developmental delays past age 2y
        - Complications such as intraventricular hemorrhage (Grade III or higher)/stroke/seizures/asphyxia, etc.
    - Radiation therapy to the central nervous system
    - Sickle cell disease
    - Small for gestational age/Intrauterine growth restriction (SGA/IUGR) (2)
    - Stroke
    - Sydenham's Chorea
    - Tourette's Syndrome
    - Toxin exposure - carbon monoxide poisoning, Fetal Alcohol Syndrome or Fetal Alcohol Spectrum Disorder (requires documented exposure), prenatal exposure to cocaine or methamphetamine as evidenced by positive tox screen in pregnancy or at birth, or withdrawal symptoms at birth (2)
    - Traumatic brain injury (1)

- Neuropsychological testing is NOT indicated for ANY of the following conditions:
    - **Autism**: testing is not routinely indicated in the absence of other indications for this type of testing. For autism specific evaluation, have parents complete appropriate screening and place Ref Peds, Developmental Pediatrics.
    - Neuropsychological testing for **learning disabilities (ie Dyslexia) and/or ADHD** in the absence of a qualifying medical diagnosis is not a covered benefit.

Notes:

(1) Managed by CHCO Rehabilitation Neuropsychology team.
(2) Should consider Neuropsychology evaluation by National Jewish (Patients in Central or South areas) or John Kirk (Patients in the North Area)
(3) Managed through eXtraordinary Kids Clinic (CHCO Developmental Pediatrics)
(4) Rocky Mountain Neuropsychology Consultants

Referrals

Kaiser contracts with a number of external providers for neuropsychological testing.

- For questions about pediatric neuropsychological testing, use REF PEDS DEVELOPMENTAL PEDIATRICS for advice referral
- To initiate a referral, enter REF Peds Neuropsychological Test in Health Connect and indicate referral for neuropsychological testing and medical indications for referral in comments.

Citations

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HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Routine update and formalization by UM Committee. Dr. R. Nolan (developmental pediatrics) primary author.	02.2021
1.1	Added pre/peri-natal infections per Dr. Nolan	06.2021
1.2	Minor edits in wording and updated resources	08.2023
1.3	Approved by: KPCO Utilization Management Committee added and updated Notes (will see Teens) taken out after Rocky Mountain Neuropsychology Consultants as they are now seeing peds and teens.	08.2023
2.0	Annual review, no changes made	09.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Evaluation of Orofacial Surgery Referrals

Sub department(s): Utilization Management Medical Directors	Last Review: 10.2024 Next Review: 10.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Evaluation of Orofacial Surgery Referral Requests

This guideline was developed to support clinician and utilization review teams about appropriate use of orofacial surgery referral requests. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Requests for Orofacial Surgery services must meet **ONE OR MORE** of the following criteria:

1. Requests for orofacial surgical consultation visits must meet ALL of the following:

    a. The request includes at least one potentially covered service (i.e. the request is not solely for non-covered services).
        i. Routine dental care (extractions, root canals, restorations, etc.) are not covered services.
        ii. Care for cleft lip and palate is covered, so long as the services provided are incident-to the cleft defect (i.e. routine dental implants are covered for the area of the cleft (midline) but not distant from it).
        iii. Care for accidental injury to teeth may be covered and is dependent on the member's EOC.
        iv. Orthodontic treatment is not a covered service, including braces and corrective appliances.
        v. Occlusal Equilibration (procedures on teeth only for purposes of improving contact between teeth) is not a covered service.
            1. Often coded D9950, D9951, or D9952 or 41899 (unlisted procedure dentoalveolar structures)
        vi. Prosthetic dentistry may be covered after extensive bony removal during head and neck cancer surgery.
        vii. Tooth Extraction including Full Mouth Extraction (FME) is only covered prior to head and neck irradiation for cancer treatment.

    b. If the request is for a Temporomandibular Joint (TMJ) problem, ALL of the following must be met:
        i. Conservative treatment has failed for at least 2 months, including BOTH of these:
            1. Regular use of acetaminophen or an anti-inflammatory medication, and
            2. Regular use of a soft diet
        ii. The patient has participated in at least four (4) months of a structured Physical Therapy program for TMJ dysfunction, and
        iii. Imaging (MRI or CT) showing anatomic abnormality of the TM joint.

2. Requests for orofacial surgical procedures must meet ONE OR MORE of the following:

a. Requests for surgery involving the Temporomandibular Joint (TMJ) must meet ALL of the following:
    i. Jaw opening restricted to < 35mm
    ii. TM joint pain is localized, continuous, and described as moderate to severe
    iii. TM joint pain worsens during jaw function (e.g. chewing, talking).

b. Requests for orofacial surgical procedures not limited to the Temporomandibular Joint (TMJ) must meet ALL of the following:
    i. Documentation of functional problem, including but not limited to patient's inability to chew, chews with pain, TMJ pain due to anatomic deformity, etc.
        1. *Requests that appear to be purely orthodontic or cosmetic in nature, where no functional problems are documented, are denied as not a covered benefit. Orthodontic and cosmetic procedures are benefit exclusions.*
    ii. The request does not include Genioplasty (chin augmentation) or mentoplasty (chin reduction) codes. These are cosmetic procedures and are not covered.
    iii. Documentation states that orthodontia or equivalent non-surgical measures are not fixing the functional problem.
    iv. If Sleep Apnea is present, must have documentation that CPAP has been tried and has failed to adequately address symptoms of Sleep Apnea.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Created OMFS Guideline. Consulted with John Clark, MD. Approved by KPCO Guideline Committee on 10/29/18.	10.2018
1.1	Annual update	10.2019
2.0	Incorporation of separate TMJ GL into this GL for clarity of reviews, and retirement of the separate GL.	06.2020
2.1	Routine review	03.2021
2.2	Routine review, clarified 'occlusal equilibration'	02.2022
2.3	Added 1.a.ii to reflected mandated coverage for cleft lip & palate	06.2022
2.4	Minor edits, annual review	10.2023
2.5	Annual Review	10.2024

Utilization Management Department

KPCO Criteria for CYP2D6 Pharmacogenomic Testing

Sub department(s): Utilization Management Medical Directors

Last Review: 09.2024

Next Review: 09.2025

Approved by: KPCO Utilization Management

Title:

KPCO Criteria for CYP2D6 Pharmacogenomic Testing

This guideline was developed to support clinician and utilization review teams about appropriate use of CYP2D6 Pharmacogenomic Testing. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for CYP2D6 Pharmacogenomic Testing

CYP2D6 Pharmacogenomic Testing may be considered if ALL of the following are met:

1. Provider ordering the test MUST meet ALL of the following criteria:

- The treating clinician who is responsible for pharmacologic management of patient's condition
- Has licensure, qualifications, and necessary experience/training to both diagnose condition being treated and prescribe medications for condition.

2. Patient has a condition that clinical evaluation has determined need for medication with known gene-drug interaction(s) AND for which test results would directly impact drug management of patient's condition.

- Medications currently known to have an interaction with CYP2D6 as defined by a Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline level A or B[1] or by FDA inclusion their table of known gene-drug interactions where data support therapeutic recommendations or potential impact on safety or response[2] are:
  - amitriptyline
  - amphetamine
  - aripiprazole
  - atomoxetine
  - brexpiprazole
  - carvedilol
  - cevimeline
  - clomipramine
  - clozapine
  - codeine
  - desipramine
  - deutetrabenazine
  - doxepin
  - eliglustat
  - fluvoxamine
  - gefitinib

- haloperidol
- hydrocodone
- iloperidone
- imipramine
- lofexidine
- meclizine
- metoclopramide
- oliceridine
- paroxetine
- perphenazine
- pimozide
- pitolisant
- propafenone
- ondansetron
- nortriptyline
- risperidone
- tamoxifen
- tetrabenazine
- thioridazine
- tolterodine
- tramadol
- trimipramine
- tropisetron
- valbenazine
- venlafaxine
- vortioxetine

3. Patient has not previously had clinical grade CYP2D6 genotyping performed

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline by A. Quinn, PharmD References (1) https://cpicpgx.org/genes-drugs/, and (2) Table of Pharmacogenetic Associations | FDA	04.2022
2.0	Added haloperidol and risperidone, additional reference (1) Pharmacogenomic Recommendations for Psychiatry / Behavioral Health – Interregional Practice Recommendations | CO Clinical Library (kp.org)	9.2024

Utilization Management Department
KPCO Criteria for Plastic Surgery Procedures – Commercial

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Selected Plastic Surgery Procedures

This guideline was developed to support clinician and utilization review teams about appropriate use of Selected Plastic Surgery Procedures. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Selected Plastic Surgery Procedures.

Medical Necessity for covered, functional Plastic Surgery procedures may be considered if ANY of the following are met:

1. **Rhinoplasty**: See MCG A0182, A0184 or L35090.

2. **Abdominoplasty or Panniculectomy:** See MCG A0497, A0498 or L35090.

3. **Blepharoplasty**, **Canthoplasty**, and related eye procedures: See MCG A0195 or L35004.

4. **Otoplasty** may be indicated when ALL of the following are met:
    a. Reconstruction or repair of birth defect up to age 18 or injury
    b. Some documented functional benefit is expected:
        i. Includes hearing, glasses (if visual impairment is present), use of hearing aids (if hearing impairment is present)

5. **Treatment of Facial Paralysis** from congenital, post-surgical, or trauma related causes with Botox may be indicated if ONE of the following is met:
    a. Documented functional impairment (e.g. impaired blink reflex, drooling, etc), or
    b. Synkinesis, when firing one muscle group leads to the unintentional and undesirable firing of another muscle group.

6. **Breast Reduction** (Mammoplasty, Mammaplasty) may be indicated when EITHER A, B and C are met or D is met:
    a. At least six months of physical or functional impairment related to macromastia, as shown by ANY of the following:
        i. Shoulder, neck or back pain
        ii. Recurrent severe mammary intertrigo (forming abscess or requiring antibiotics) despite adequate medical treatment
    b. Failure of conservative therapy to adequately control impairment, as shown by all of the following:
        i. Weight loss
        ii. Regular use of adequate support garments
        iii. Exercise and/or Physical Therapy
        iv. Regular NSAID treatment
        v. Cosmetic breast implants need to be removed prior to glandular reduction at patient's expense
    c. Expected tissue removal is estimated by the surgeon to be at least 400gm or meets Schnur criteria for patients under BSA 1.91
    d. Gigantomastia of Pregnancy may qualify for reduction mammoplasty when ALL of the following are met:
        i. Breasts are enlarged beyond the pre-pregnancy size
        ii. A qualifying complication is present, including ANY of the following:
            1. Massive infection
            2. Significant hemorrhage
            3. Tissue necrosis with slough
            4. Ulceration of breast tissue.
        iii. Signs or symptoms have been present for at least 6 months
        iv. Medical treatment or physical interventions have not adequately alleviated symptoms.

7. **Explantation of Breast Implants** may be indicated for ANY of the following conditions:
    a. Implant rupture,
    b. Infection of the breast extending to the implant,
        i. superficial cellulitis of the breast is not an indication for removal.
    c. Baker Grade 4 capsular contracture, or
    d. Other recognized medical complication where there is some functional impairment and no reasonable alternative but to remove the implant.

8. **Diastasis Recti** repair may be indicated if ALL of the following are met:
    a. Severe diastasis >5cm,
    b. Patient has severe functional impairment related to diastasis,
    c. In the surgeon's opinion, surgical correction of the diastasis is likely to provide relief of the significant functional impairment related to the diastasis, and
    d. A limited surgical approach is planned;
        i. Abdominoplasty procedure is not indicated for this diagnosis.

9. **Fat transfer grafting** for Localized Scleroderma (Parry-Romberg Syndrome, others) may be indicated when ALL of the following are met:
    a. Functional benefit is expected, including but not limited to:
        i. Lesions are causing impairment joint movement,
        ii. Lesions are causing functional impairment of chewing or swallowing
    b. Failure of at least 6 months of medical therapy.

10. **Scar revisions** from trauma or previous surgery may be indicated when A is met and ONE of criteria B, C, or D is met:
    a. The requested procedure is not for acne related scar.
    b. The scar is causing contractures, distortion of adjacent structures, or has healed abnormally due to infection or secondary intention.
    c. The scar is on the face and is causing significant disfigurement and revision can achieve more than minimal improvement, or
    d. The scar is a keloid or hypertrophic scar.

11. Tissue removal after **Bariatric Surgery** (thigh lift, brachioplasty / arm lift) may be indicated when ALL of the following are met:
    a. Patient has complications from excess skin (eg, severe chronic intertrigo, skin infection, ulceration (forming abscess or requiring antibiotics) that has been persistent despite nonsurgical treatment).
    b. Pannus interferes with walking beyond simply back, knee, or hip pain.
        i. A pannus that covers the genitalia does not automatically constitute a functional problem
    c. Patient's weight has reached stable plateau, and 1 or more of the following:
        i. Adherence to multidisciplinary nonsurgical program of weight maintenance
        ii. One year or more has elapsed following bariatric surgery and 3 months of stable weight
    d. The amount of tissue to be excised would be a similar amount to that which would be excised for a covered abdominal pannus excision.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline based on information provided by Drs. M Kiehn and R. Gerow.	01.2021
1.1	Routine yearly review, minor clarifications made	02.2022
1.2	Review after L35090 updated 3/22, no updates needed.	04.2022
1.3	Routine maintenance. Clarification for Medicare	04.2024

Utilization Management Department
KPCO Process Flow for TPN, IPN, IDPN Requests

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved: KPCO UM Committee

Title:
KPCO Process for TPN, IPN, IDPN Requests

This process flow. was developed to support clinician and utilization review teams about appropriate use of requests for TPN, IPN, IDPN.

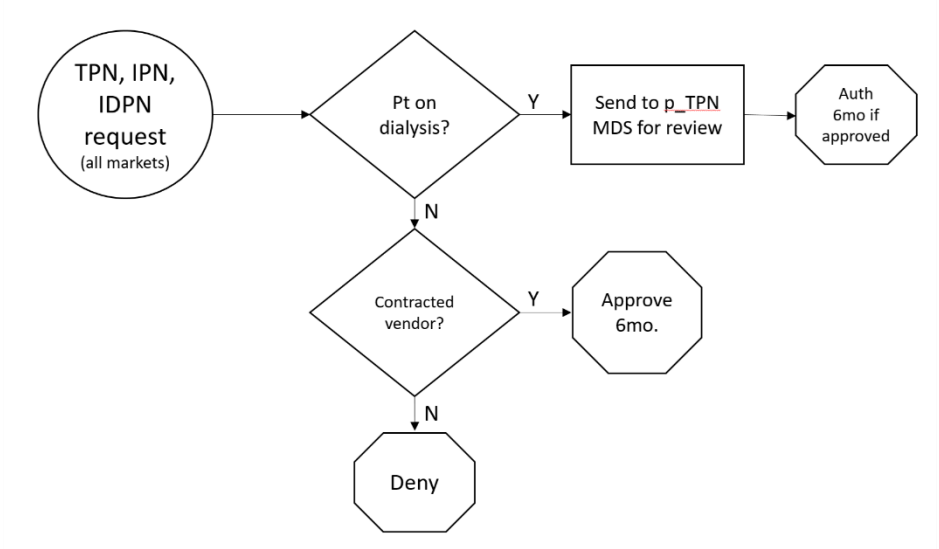
Criteria for TPN, IPN, IDPN Requests

A request for TPN, IPN, or IDPN may be considered if (1) is met and EITHER (2) or (3) is met:

1. If a non-contracted vendor is requested, the patient must be physically located outside of Colorado.
    a. Deny if the request is for a non-contracted provider and the patient is physically located in Colorado. Services are available from contracted providers.
    b. If the provider is non-contracted AND the patient is physically outside Colorado, proceed to # 2.

2. For patients on dialysis: send the request to p_TPN MDS
    a. Approve for 6 months if approved by the TPN physician.
    b. Send for UMMD denial if the TPN MD requests denial.

3. For patients not on dialysis:
    a. Approve TPN for 6 months to contracted vendor.
    b. Send for UMMD denial or consideration of other extenuating circumstances if the vendor is not contracted.



HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, consultation with Dr. K Froyd, Medical Director Pharmacy Utilization & Therapeutics.	07.2021
1.1	Routine review	04.2022
1.2	Deny non-con vendors unless patient is OOA. Discussion with Dr. K. Froyd, PU&T.	05.2023
1.3	Routine maintenance, clarification that this is a process document, not a guideline	04.2024

Utilization Management Department
KPCO Criteria for Prostate Cancer Biomarker Testing

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Prostate Cancer Biomarker Testing

This guideline was developed to support clinician and utilization review teams about appropriate use of Prostate Cancer Biomarker Testing. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Prostate Cancer Biomarker Testing

Biomarker Testing is appropriate in the following situations:

1. Prostate Health Index (ARUP), all of these:
    a. PSA over age-adjusted normal on two tests, > 1 month apart
        i. 40-59 > 2.5
        ii. 50-59 > 3.5
        iii. 60-69 > 4.5
        iv. Over 70 > 6.5
    b. And PSA < 10.0
2. ConfirmMDx (MDx Health), either of these:
    a. Negative prostate biopsy and
        i. Rising PSA
        ii. Being considered for MRI or repeat biopsy, or
    b. Intermediate prostate biopsy with HGPIN, ASAP, or Atypia.
3. Oncotype Dx (Genomic): indicated for positive biopsy prior to surgery.
4. Decipher Prostate (Veracyte): indicated for surgical sample obtained after a positive biopsy.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline: based in SCAL decision path, J. Green MD (Urology) contributing.	2.2024

SUPPORTING EVIDENCE:

Up to Date: “Molecular Prognostic Tests for Prostate Cancer” [https://www.uptodate.com/contents/molecular-prognostic-tests-for-prostate-cancer?search=prostate%20cancer%20biomarkers&sectionRank=3&usage_type=default&anchor=H40176827&source=machineLearning&selectedTitle=1%7E150&display_rank=1#H40176827]

Up to Date: “Localized prostate cancer: Risk Stratification and Choice of Initial Treatment” [https://www.uptodate.com/contents/localized-prostate-cancer-risk-stratification-and-choice-of-initial-treatment?search=prostate%20cancer%20biomarkers&source=search_result&selectedTitle=5%7E150&usage_type=default&display_rank=5]

Utilization Management Department
KPCO Criteria for Advanced Imaging for Prostate Cancer

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Advanced Imaging for Prostate Cancer

This guideline was developed to support clinician and utilization review teams about appropriate use of **Advanced Imaging for Prostate Cancer.** It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Advanced Imaging for Prostate Cancer

Imaging for Prostate Cancer may be considered if ONE of the following are met:

1. Initial Staging Evaluation and Assessment for Metastatic Disease
    a. NCCN high- or very-high risk disease = Stage T3a or higher or Gleason 8-10 or PSA > 20:
        i. First Line: bone scan + CT Chest/Abd/Pelvis with contrast.
        ii. PSMA (Prostate-Specific Membrane Antigen - Pylarify or Gallium-68): first line imaging is negative and concern remains for metastatic disease.
    b. NCCN unfavorable disease = cT2B-T2c or Gleason 7 or PSA 10-20 or >/= 50% of core biopsies are positive for cancer:
        i. PSMA (Pylarify or Gallium-68) or First Line imaging are acceptable.
    c. NCCN favorable disease: anything not fitting above criteria:
        i. First Line imaging is indicated.
        ii. PSMA (Pylarify or Gallium-68) requires approval by GU Tumor Board or GU ECCC (Excellence in Cancer Care Council) committee.

2. Biochemical Recurrence and Subsequent Treatment Strategy
    a. PSA >/= 0.5 ng/ml after prostatectomy:
        i. First Line imaging should be performed again.
        ii. PSMA (Pylarify or Gallium-68) can be approved if BOTH of the following are met:
            1. Salvage EBRT is planned or being considered, and

2. PSA < 50 OR First Line imaging is equivocal or indeterminate.

iii. Axumin PET/CT: First Line and PSMA are equivocal or indeterminate.

b. Serologic Relapse after EBRT or Brachytherapy = PSA rise of 2 ng/ml or more above lowest point after treatment:
   i. First Line imaging should be performed again.
   ii. PSMA (Pylarify or Gallium-68) can be approved if BOTH of the following are met:
      1. Salvage surgery is planned or being considered, and
      2. PSA < 50 OR First Line imaging is equivocal or indeterminate.
   iii. Axumin PET/CT: First Line and PSMA are equivocal or indeterminate.

c. Known or suspected oligometastatic disease with plan for radiation therapy, not meeting above criteria:
   i. First Line imaging should be performed again.
   ii. PSMA (Pylarify or Gallium-68) can be approved if BOTH of the following are met:
      1. Radiation Oncology would consider treatment of oligometastatic disease if confirmed, and
      2. PSA >/= 0.5 ng/ml and PSA has doubled in 3 months or more
         a. *Note: PSA doubling faster than 3 months often means distant metastasis where local radiation is not appropriate.*
   iii. Axumin PET/CT only considered if PSMA PET/CT cannot be done for some reason

3. Non-Metastatic Castration-Resistant Prostate Cancer (CRPC):
   a. First line imaging should be done initially.
   b. PSMA (Pylarify or Gallium-68) can be approved if EITHER of the following are met:
      i. First Line imaging negative and PSA doubling time is less than 10 months, or
      ii. Radiation Oncology would consider treatment of oligometastatic disease if confirmed
      iii. Axumin PET/CT only considered if PSMA PET/CT cannot be done for some reason
4. Known Diffuse or non-oligometastatic castrate-resistant prostate cancer:
   a. PSMA (Pylarify or Gallium-68) PET/CT is required prior to consideration for PSMA Lutetium for **CRPC**.

i. *Current FDA approval for PSMA Lutetium is only for CRPC. For patients with CSPC, Lutetium is not currently approved, and only used in a clinical trial setting.*

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, criteria developed by GU Oncology Group (medical oncology, urology, radiology, radiation oncology), email 7/2022 Dr. M. Eadens	8.2022
1.1	Review done by Dr. Swan Davis, D.O., UMMD - section 2.b.ii.1, changed “EBRT” to “surgery” and section 4.a.i, changed the wording after discussion with Dr. Matthew Eadens via email	8.2023
1.2	Routine annual review – no changes made	9.2024

Utilization Management Department
KPCO Criteria for Use of Remdesivir for COVID-19 Treatment or Prophylaxis

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Remdesivir for COVID-19 Treatment or Prophylaxis

This guideline was developed to support clinician and utilization review teams about appropriate use of Remdesivir for COVID-19 Treatment or Prophylaxis. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Remdesivir for COVID-19 Treatment or Prophylaxis

Remdesivir for COVID-19 Treatment or Prophylaxis may be considered when ALL of the following are met:

1. Patient has **7 days or fewer** of COVID-19 symptoms, and
2. Patient is not hospitalized, and
3. The patient weighs at least 3.0kg (7.0 lbs; remdesivir is approved for children), and
4. The patient has at least one risk factor for severe COVID-19 disease, including any of these:
    a. Age >/= 60
    b. BMI > 25.0 (or children > 85th percentile for age)
    c. Diabetes Mellitus (not pre-diabetes or impaired glucose tolerance)
    d. Hypertension diagnosed and documented.
    e. CKD with GFR < 60
    f. Cardiovascular disease, meaning diagnosed and documented coronary artery disease (CAD) or peripheral arterial disease (PAD).
    g. Any chronic respiratory disease, including persistent asthma, emphysema, COPD and others for which controller medication is required.
    h. Dementia diagnosed and documented.
    i. Any active cancer diagnosis
    j. Any chronic liver disease diagnosed and documented.
    k. Current or Former smoker

l. Immunocompromised (usually by chemotherapy, infusions for chronic disease, or anti-rejection medications).
m. Any neurodevelopmental disorder, including Cerebral Palsy and others.
n. HIV, any stage or status.
o. Diagnosis of sickle cell disease or thalassemia
p. History of stroke with residual deficits
q. Current substance use disorder
r. Currently pregnant.
s. Any dependence on medical technology (tracheostomy, gastrostomy, need for ventilation).

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline based on Lexicomp off-label use and risk factors from mAb guideline.	01.2022
1.1	Routine maintenance, Dr. A. Duckro involved	04.2024

SUMMARY EVIDENCE:

(Nonhospitalized Adults: Therapeutic Management | COVID-19 Treatment Guidelines (nih.gov).

Up to Date LexiDrug: Remdesivir [https://online.lexi.com/lco/action/doc/retrieve/docid/kaico_f/6947448?cesid=4EEgdxT7tOM&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dremdesivir%26t%3Dname%26acs%3Dtrue%26acq%3Dremdes]

Utilization Management Department
KPCO Criteria for Rezum® (thermal vapor) treatment for Benign Prostatic Hypertrophy

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2024 Next Review: 08.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Rezum® (thermal vapor) treatment for Benign Prostatic Hypertrophy

This guideline was developed to support clinician and utilization review teams about appropriate use of Rezum® (thermal vapor) treatment for Benign Prostatic Hypertrophy. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Rezum® (thermal vapor) treatment for Benign Prostatic Hypertrophy (BPH)

Rezum® water vapor thermal energy treatment may be approved for BPH if ALL of the following are met:

1. Documentation of Lower Urinary Tract Symptoms (LUTS) including but not limited to urinary urgency, frequency, incomplete emptying, intermittency (starting & stopping during urination), weak stream, and/or straining to empty the bladder.
2. Prostate volume documented as less than 80 gm.
3. Patient has been counseled regarding surgical options for BPH with LUTS (e.g. Transurethral Resection of the Prostate (TURP), etc).

Supporting Research

Water vapor thermal therapy:

Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g; however, patients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited. [1] This treatment can be offered to patients considering traditional transurethral resection of the prostate (TURP) or other surgical treatments.

Water vapor thermal therapy, using the Rezum® system, can be performed in an office setting. A 3 year prospective, randomized control trial showed IPSS improvements at 3 months were significant (-11.2 point reduction vs -4.3 point reduction in control group), P < 0.0001. These

improvements were sustained at three years. Corresponding and durable improvements were seen in urinary flow rate (Qmax), quality of life, and incontinence assessments. The surgical retreatment rate was reported at 4.4% over three years. Ejaculatory dysfunction rates were not affected in the three year followup.[2,3]

Water vapor thermal therapy using the Rezum® system can be offered to men with prostate volume < 80 g providing adequate counseling regarding efficacy as compared to traditional TURP surgery. Though ejaculatory dysfunction rate is likely lower with this treatment modality, patients should still be counseled that this is a risk of treatment. Large median lobe component of BPH is not a contraindication to this therapy. Current data do not support this therapy in the setting of urinary retention and catheter dependence. However, this can be considered a treatment option for men who are not medically fit for other surgical options.

References:

1. Harris E. Foster, MD; Michael J. Barry, MD; Manhar C. Gandhi, MD; Steven A. Kaplan, MD; Tobias S. Kohler, MD; Lori B. Lerner, MD; Deborah J. Lightner, MD; J. Kellogg Parsons, MD; Claus G. Roehrborn, MD; Charles Welliver, MD; Kevin T. McVary, MD. Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia. 2018. https://www.auanet.org/guidelines/benign-prostatic-hyperplasia/lower-urinary-tract-symptoms-(2018)

2. McVary KT, Roehrborn CG. Three-Year Outcomes of the Prospective, Randomized Controlled Rezūm System Study: Convective Radiofrequency Thermal Therapy for Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia. Urology 111: 1-9, 2018.

3. Gupta N, Rogers T, Holland B, Helo S, Dynda D, McVary KT. Three-Year Treatment Outcomes of Water Vapor Thermal Therapy Compared to Doxazosin, Finasteride and Combination Drug Therapy in Men with Benign Prostatic Hyperplasia: Cohort Data from the MTOPS Trial. J Urol 200, 405-413, August 2018.

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline with research and input by Dr. Dall'era, ASC Urology	07.2020
1.1	Routine review, updated with RSC M. Chen, no change	07.2021
1.2	Routine review by Swan Davis, D.O., UMMD. No change	08.2023
1.3	Routine annual review. No changes needed per KP Urology Medical Director, Dr. Justin Green	08.2024

RESOURCE STEWARDSHIP
KPCO Criteria for Sleep Studies (Polysomnogram) - Commercial

Sub department(s): Utilization Management MD	Last Review: 04.2024 Next Review: 04.2025 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Sleep Studies (Polysomnogram)

Criteria for Sleep Studies

In-home PSG (sleep study) may be indicated if ALL of the following are met:

1. Adult with suspected obstructive or central sleep apnea, as indicated by **1 or more** of the following:
    a. Epworth sleepiness score of 11 or greater
    b. Excessive daytime sleepiness, fatigue or awakenings with gasping or choking
    c. Hypertension that is uncontrolled despite 3-drug regimen that includes diuretic
    d. Witnessed apnea or choking episodes
    e. Postoperative assessment needed after performance of surgery to treat obstructive sleep apnea
    f. Significant oxygen desaturation (i.e. average < 90%) or > 30 min with saturation <89% on overnight pulse oximetry
    g. Snoring
    h. Obesity, defined as BMI >/= 30.
2. Patient has ability to manage the home testing equipment.

In-lab diagnostic polysomnogram or split night study (95810 or 95811) may be indicated if ANY of the following are met:

1. Adult with suspected obstructive or central sleep apnea who meets above criteria for home sleep apnea testing AND has a mental or physical inability/limitation to perform an ambulatory sleep study (e.g. musculoskeletal disability, intellectual disability, blindness, dementia, inadequate sleep environment)

2. Child, infant or neonate with suspected obstructive sleep apnea, and **1 or more** of the following:
    a. Adenoid or tonsillar enlargement, and adenoid+/-tonsillectomy is being considered for treatment
    b. Craniofacial malformation
    c. Down syndrome
    d. Neuromuscular disorder
    e. Signs and symptoms consistent with obstructive sleep apnea, including **1 or more** of the following:
        i. Daytime sleepiness
        ii. Nocturnal enuresis
        iii. Failure to thrive (weight less than 5th percentile for age)
        iv. Hyponasal speech
        v. Mouth breathing
        vi. Nocturnal pauses in breathing
        vii. Nonspecific behavioral problems (e.g. hyperactivity, developmental delay, aggression, poor school performance)
        viii. Pulmonary hypertension
        ix. Signs of increased respiratory effort (i.e. nasal flaring)
        x. Snoring

3. Suspected narcolepsy or idiopathic hypersomnia
4. Suspected parasomnia
5. Suspected periodic limb movement disorder
6. History of a negative ambulatory sleep study with persistent clinic suspicion of obstructive sleep apnea
7. Postoperative assessment needed after performance of surgery to treat sleep apnea in a child, as indicated by 1 or more of the following:
    a. Apnea-hypopnea index or respiratory disturbance index 20 or greater on preoperative PSG
    b. BMI greater than 95th percentile for age(81)
    c. Craniofacial anomalies that obstruct upper airway
    d. Neurologic disorder (eg, Down syndrome, Prader-Willi syndrome, myelomeningocele)
    e. Persistent apnea witnessed after surgery
    f. Rapid maxillary expansion
8. Pre-operative assessment to assess appropriateness for hypoglossal nerve stimulator surgery (Inspire® , others)

In-lab Multiple Sleep Latency Test (MSLT) (95805) may be indicated if ALL of the following are met:

1. Suspected disorder of hypersomnolence (e.g. narcolepsy, idiopathic hypersomnia, Klein Levin Syndrome) **AND** must be preceded by a diagnostic PSG or titration study the night before

In-lab titration study (95811) may be indicated if ALL of the following are met:

1. Persistently high AHI/persistent EDS with use of auto-titrating PAP
2. Need to try alternative modality (e.g. bilevel, bilevel ST, adaptive servoventilation)
3. Evidence of persistent hypoxemia despite PAP use.

References

- Polysomnography (PSG), Portable or Home Sleep Study, A-0144 (MCG, 23rd ed.)
- Polysomnography (PSG), Sleep Center, A-0145 (MCG, 23rd ed.)

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	MCG GL modified with help of Dr S Richey, Dr J Wilkin	04.2019
2.0	MCG for children added with Dr S. Richey	07.2020
2.1	Added point 8, testing indicated prior to hypoglossal nerve stimulator surgery	02.2021
2.2	Routine review, minor changes from S. Richey, ASC Sleep	07.2021
2.3	Routine review, Dr. S. Richey	04.2022
2.4	Routine maintenance , clarification to use with Commercial only	04.2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria: Total Hip Arthroplasty

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

Medicare Members

CMS Coverage Manual	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	L36007 Lower Extremity Major Joint Replacement
Other Pertinent Documents	A56796-Billing & Coding Lower Extremity Major Joint Replacement (Hip and Knee)

Non-Medicare Members

Total Hip Arthroplasty is medically necessary when the following criteria are met:

1. Pain and functional disability that interferes with Activities of Daily Living (ADL's) due to osteoarthritis, rheumatoid arthritis, avascular necrosis, or post-traumatic arthritis of the hip joint, AND
2. Limited range of motion (ROM), antalgic gait, and pain with passive ROM on physical examination, AND meeting one of the following categories (a.-e.):
    a. Advanced joint disease demonstrated by all of the following:
        i. Radiographic or imaging evidence in the last 12 months showing moderate to severe osteoarthritis; Xray findings should show at least one of the following:
            1. Subchondral cysts or sclerosis
            2. Periarticular osteophytes
            3. Joint subluxation
            4. Bone-on-bone articulation
            5. Moderate to severe joint space narrowing, or
            6. Tonnis Grade 2 or 3 osteoarthritis (meaning cysts in femoral head or acetabulum, narrowing of joint space, lost sphericity of femoral head, or avascular necrosis).
        ii. Documentation of the failure of non-surgical conservative management as shown by ALL of the following:

1. Analgesic medication at therapeutic doses for more than 3 weeks, including at least one of the following:
    a. NSAID drugs oral or topical unless contraindicated,
    b. Acetaminophen, or
    c. Intra-articular corticosteroid injection.
2. A trial of at least 3 Physical Therapy visits OR clear documentation as to why such approach is not reasonable, which may be one of the following:
    a. Rapid progression or advancement of radiographic arthritic severity, or
    b. Rapid or progressive flexion contraction, or
    c. Medical or social confounding factors that preclude the safety or feasibility of conservative treatment.
3. Patient must meet all of the following:
    a. BMI < 35, or if BMI > 35 documentation of i. and ii. or iii.:
        i. Sustained weight loss over at least 3 months or documented active participation in a weight loss or active exercise program.
        ii. Formal nutritional counseling.
        iii. OR documentation of risks specific to uncontrolled diabetes through shared decision-making.
    b. HBA1C < 7.5 or if HBA1C > 7.5 documentation of one of the following:
        i. Reduction in A1C over the last 6 months, or
        ii. Documentation of risks specific to uncontrolled diabetes through shared decision-making.
    c. No nicotine use for 30 days prior to surgery or documentation that the patient is actively involved in a nicotine cessation program with at least 90% reduction in nicotine use, or documentation of risks specific to nicotine use through shared decision-making.

b. Avascular Necrosis: radiographic evidence of AVN / bone infarct.
c. Inflammatory Arthritis (may include RA, psoriatic, spondyloarthropathy, gout/pseudogout, lupus, non-DJD arthritis, hemophilia-related arthritis)
    i. Patient is actively followed by Rheumatology and has been judged to have exhausted non-surgical options including DMARDs.
    ii. Radiographic evidence in the last 12 months showing moderate to severe OA, including at least one of the following:
        1. Subchondral cysts or sclerosis
        2. Periarticular osteophytes
        3. Joint subluxation
        4. Bone-on-bone articulation
        5. Moderate to severe joint space narrowing, or

6. Tonnis Grade 2 or 3 osteoarthritis (meaning cysts in femoral head or acetabulum, narrowing of joint space, lost sphericity of femoral head, or avascular necrosis).

iii. A trial of at least 3 Physical Therapy visits OR clear documentation as to why such approach is not reasonable, which may be one of the following:
   1. Rapid progression or advancement of radiographic arthritic severity, or
   2. Rapid or progressive flexion contraction, or
   3. Medical or social confounding factors that preclude the safety or feasibility of conservative treatment.

iv. Patient must meet all of the following:
   1. BMI < 35, or if BMI > 35 documentation of i. and ii. or iii.:
      a. Sustained weight loss over at least 3 months or documented active participation in a weight loss or active exercise program.
      b. Formal nutritional counseling.
      c. OR documented shared decision making conversation between the patient and the surgeon with documentation of risks.
   2. HBA1C < 7.5 or if HBA1C > 7.5 documentation of one of the following:
      a. Reduction in A1C over the last 6 months, or
      b. Documentation of risks specific to uncontrolled diabetes through shared decision-making.
   3. No nicotine use for 30 days prior to surgery or documentation that the patient is actively involved in a nicotine cessation program with at least 90% reduction in nicotine use, or documentation of risks specific to nicotine use through shared decision-making.

d. Revision of previous arthroplasty, with all of the following:
   i. Patient has any of the following indications:
      1. Aseptic loosening of one or more components confirmed by imaging
      2. Symptomatic synovitis or local bone or soft tissue reaction caused by bearing surface wear
      3. Component instability
      4. Peri-prosthetic fracture
      5. Fracture, mechanical failure, or recall of a component
      6. Peri-prosthetic infection
      7. Progressive or substantial peri-prosthetic bone loss
      8. Recurrent or irreducible dislocation
      9. Recurrent, disabling pain associated with clinically significant limb-length inequality or audible noise.
   ii. Conservative therapy is not indicated
   iii. Patient must meet all of the following:
      1. BMI < 35, or if BMI > 35 documentation of i. and ii. or iii.:

a. Sustained weight loss over at least 3 months or documented active participation in a weight loss or active exercise program.
b. Formal nutritional counseling.
c. OR documented shared decision making conversation between the patient and the surgeon with documentation of risks.

2. HBA1C < 7.5 or if HBA1C > 7.5 documentation of one of the following:
    a. Reduction in A1C over the last 6 months, or
    b. Documentation of risks specific to uncontrolled diabetes through shared decision-making.
3. No nicotine use for 30 days prior to surgery or documentation that the patient is actively involved in a nicotine cessation program with at least 90% reduction in nicotine use, or documentation of risks specific to nicotine use through shared decision-making.

e. Other Conditions
    i. Patient has any of the following indications:
        1. Acute hip fracture by imaging.
        2. Conversion of prior hip surgery due to progression of disease or failure, including any of these:
            a. Previous open or closed reduction and internal fixation of the femur or acetabulum
            b. Intramedullary nail
            c. Hemiarthroplasty
            d. Hip resurfacing
            e. Hip fusion and resection arthroplasty (“Girdlestone” procedure)
    ii. Conservative therapy not indicated.

3. The patient must not have a condition where hip arthroplasty is contraindicated:
    a. Active infection of the hip joint or active systemic bacteremia
    b. Active skin infection within the planned surgical approach
    c. Unstable angina
    d. Dementia that interferes with successful rehabilitation
    e. Lack of caregiver or unsuitable home situation for rehabilitation
    f. Patients who are non-ambulatory at baseline.

Applicable Codes

CPT® or HCPC Codes	**Description**

27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement

History of Changes

Version Number	Description of Changes	Effective Date
1.0	Guideline creation with reference to KPWA Criteria for Total Hip Arthroplasty, review from CPMG orthopedics Drs. Hug and MacDougall, and review by VP Dr. M. Kohara	10/1/2024
1.1	Language updates for symmetry with TKA guideline	10/1/2024

Kaiser Foundation Health Plan of Colorado

Clinical Review Criteria: Total Knee Arthroplasty

This guideline was developed to support clinician and utilization review teams about appropriate use of treatment modalities for the titled subject and to administer plan benefits. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend, or change any or all these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time with or without notice. Member benefits differ by health plan contract language.

Medicare Members

CMS Coverage Manual	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	L36007 Lower Extremity Major Joint Replacement
Other Pertinent Documents	A56796-Billing & Coding Lower Extremity Major Joint Replacement (Hip and Knee)

Non-Medicare Members

Total and Partial Knee Arthroplasty may be considered if requirements 1-6 are met OR 7 is met:

1. Functional disabling pain for at least 3 months which interferes with the ability to carry out Activities of Daily living
2. Radiographic evidence of moderate to severe osteoarthritis (OA) as demonstrated by one or more of the following:
    a. Multiple osteophytes and joint space narrowing and some sclerosis, or
    b. Large osteophytes, marked joint space narrowing, and severe sclerosis, or
    c. Exposed subchondral bone (full-thickness cartilage loss with underlying reactive changes of bone)
3. Analgesic medication at therapeutic doses for more than 3 weeks, including at least one of the following:
    a. NSAID drugs oral or topical unless contraindicated,
    b. Acetaminophen, or
    c. Intra-articular corticosteroid injection.
4. A trial of at least three Physical Therapy sessions in the last 12 months OR documentation as to why PT is not reasonable
5. Patient must meet all of the following:
    a. BMI < 35, or if BMI > 35 documentation of i. and ii. or iii.:
        i. Sustained weight loss over at least 3 months or documented active participation in a weight loss or active exercise program.
        ii. Formal nutritional counseling.
        iii. OR documentation of risks specific to uncontrolled diabetes through shared decision-making.

b. HBA1C < 7.5 or if HBA1C > 7.5 documentation of one of the following:
    i. Reduction in A1C over the last 6 months, or
    ii. Documentation of risks specific to uncontrolled diabetes through shared decision-making.
c. No nicotine use for 30 days prior to surgery or documentation that the patient is actively involved in a nicotine cessation program with at least 90% reduction in nicotine use, or documentation of risks specific to nicotine use through shared decision-making.

6. The patient must not have a condition where hip arthroplasty is contraindicated:
    a. Active infection of the joint or active systemic bacteremia
    b. Active skin infection within the planned surgical approach
    c. Unstable angina
    d. Dementia that interferes with successful rehabilitation
    e. Lack of caregiver or unsuitable home situation for rehabilitation
    f. Patients who are non-ambulatory at baseline.
7. Knee Arthroplasty may be medically necessary in the following circumstances:
    a. Distal femur fracture in a patient with osteoporosis
    b. Failure of a previous proximal tibial or distal femoral osteotomy
    c. Hemophilic arthroplasty
    d. Limb salvage for malignancy
    e. Post-traumatic knee joint destruction
    f. Avascular necrosis of the tibial or femoral condyle
    g. Inflammatory arthritis

Applicable Codes

CPT® or HCPC Codes	Description
27438	Arthroplasty, patella; with prosthesis
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee

History of Changes

Version Number	Description of Changes	Effective Date
1.0	Guideline creation with reference to KPWA Criteria Total Knee Arthroplasty, review by orthopedics Drs. Hug and MacDougall, and review by VP Dr. M. Kohara	10/1/2024
1.1	Language updates for symmetry with THA guideline	10/1/2024

Utilization Management Department
KPCO Criteria for Whole Exome and Whole Genome Sequencing Tests

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2024 Next Review: 09.2025 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Whole Exome and Whole Genome Sequencing Tests

This guideline was developed to support clinician and utilization review teams about appropriate use of Whole Exome and Whole Genome Sequencing tests. It is not intended to replace a clinician's clinical judgment or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by this guideline.

Criteria for Whole Exome and Whole Genome Sequencing Tests

Whole exome sequencing (WES) or Whole Genome Sequencing (WGS) may be considered when ALL of the following criteria are met:

1. Individual has been evaluated by a board-certified specialist physician specialist (most commonly geneticist or neurologist) with specific expertise in the conditions and relevant genes for which testing is being considered. Genetic counseling occurs around risks and benefits, and to review results of testing.
    a. Note/order will provide review of previous testing completed, major diagnostic features or suspected syndromes, and rationale for pursuing WES testing

2. Documentation shows that WES results will directly impact clinical decision-making and ongoing care for the individual being tested

3. A genetic etiology is the most likely explanation for the phenotype as demonstrated by ANY of the following:
    a. Multiple abnormalities affecting unrelated organ systems
    b. Complex neurodevelopmental disorder: Autism Spectrum Disorder (ASD)/Intellectual Disability (ID)/Global Developmental Delay (GDD) plus at least ONE of the following:
        i. Co-morbid medical conditions such as epilepsy, growth abnormalities, systemic disease
        ii. Severe neuropsychiatric condition

iii. Presence of multiple congenital anomalies, e.g. dysmorphic features

c. Family history strongly implicating genetic etiology

4. No other causative circumstances explain symptoms

5. Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing is available, or targeted panel does not explain symptoms.

6. The differential diagnosis list and/or phenotype warrant testing of multiple genes and ONE of the following:
   a. WES is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis
   b. WES results may preclude the need for multiple and/or invasive procedures, follow-up, or screening that would be recommended in the absence of testing. *Examples to consider:*
      i. Poorly controlled seizure disorder with normal epilepsy panel
      ii. Neuromuscular disorder with normal targeted neuromuscular panel
      iii. Progressive medical or developmental condition not explained by the natural history of the disease or known diagnosis
      iv. Poorly controlled complex medical condition that is "difficult to diagnose"

HISTORY OF CHANGES:

Version Number	Description of Changes	Effective Date
1.0	Creation of guideline, Dr. R. Nolan, author	11.2020
1.1	Update Dr. R. Nolan, reflecting change in clinical practice not to require CMA before WES	12.2021
1.2	Update, adding WGS per practice recommendations sent by CHCO; discussed with Drs. R Nolan, C. Jelinek, and A. Yager	08.2022
1.3	Update, minor changes in language, removed preferred lab section which is no longer a cost benefit.	08.2023
1.4	Updated Approved by: KPCO Utilization Management Committee	08.2023
1.5	Routine annual review	09.2024