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Utilization Management Department
KPCO Criteria for Air Ambulance Reviews

Sub department(s): Utilization Management Medical Directors	Last Review: 09.2023 Next Review: 09.2024 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. Transportation by air saves **at least 30 minutes** compared to ground transport, OR, 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 pass a 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.

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 all four criteria 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.

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

Sub department(s): Utilization Management Behavioral Health	Last Review: 10/31/2022 Next Review: Approved By: Cindy Hobbs-Huerta, RN, MS, UM Director; Lee Clark, MD Psychiatrist

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 ADMISSION FOR TREATMENT

Applied behavioral analysis (ABA) treatment is appropriate as indicated by **ALL** the following:

1. Patient has medical diagnosis of autism spectrum disorder (ASD), and the diagnostic assessment must include **ALL** of the following:
    a. Documentation of evaluation performed by a qualified health care professional, such as a developmental pediatrician, psychologist, or psychiatrist who is experienced in the diagnosis and treatment of autism
    b. Direct observation of skills, which may include measures like the Autism Diagnostic Observation Schedule – 2nd Edition (ADOS-2) or Childhood Autism Rating Scale – 2nd Edition (CARS-2) when assessment for ASD is indicated
    c. Recent assessment of cognitive/intellectual functioning (e.g., via the Wechsler scales, DAS-II, Bayley-4, Mullen, Kaufman, DAY-C) or a reasonable explanation of why this could not be completed
    d. Recent assessment of adaptive/functional skills
    e. Developmental interview
    f. Description of how patient's behaviors are having an impact on development, communication, or adjustment such that:
        - The member cannot adequately participate in home, school, or community activities; and/or the member presents a safety risk to self or others, and
        - Less intrusive and/or less intensive behavioral interventions have been tried and have not been successful, and/or there is no equally effective alternative strategy available to address the member's behaviors

2. Patient is **ALL** the following:
    a. 16 months or older
    b. Patient's risk of imminent danger to self or others is at a level where the member can appropriately engage in ABA services. Intellectual functioning is at least one of the following:
        - No suspicion of severe/profound intellectual disability
        - Estimated IQ greater than or equal to 35.

3. Patient is assessed as appropriate for ABA and all the following have been assessed:
    a. Psychiatric symptoms are assessed, and the risk level is appropriate to engage in ABA services (for example, severe suicidal ideations are present and might be appropriate to stop ABA services in support for hospitalization)
    b. Comorbid biomedical or developmental conditions are evaluated and deemed appropriate to engage in ABA services. Cognitive or memory impairments are assessed and if identified they are appropriate for ABA services and that the member can engage in services. Baselines and functional levels are taken into consideration to where ABA services are appropriate and not custodial in nature.
    c. The member has impaired impulse control to where they will need support and skills to improve their impulse control and/or regulate actions. The member has impaired judgment in the severity of their actions or behaviors, denial, or inability to recognize the need for treatment, or understand they lack insight into the consequences of their actions. The severity will be in a range from minimal impact to daily functioning to extreme of severe impacts to daily functioning.
    d. The member presents with emotional or behavioral disturbances **by 1 or more** of the following:
        - Externalizing symptoms such as angry outbursts, physical or verbal aggression, oppositional defiant traits, agitation, or other disruptive behaviors
        - Internalizing symptoms such as isolative, apathy, rumination.
    e. The member presents with serious dysfunction in daily living and serious deterioration in interpersonal interactions as indicated **by 1 or more** of the following:
        - Significant withdrawal and avoidance of almost all social interaction
        - Consistent failure to achieve self-care as appropriate to age or developmental level
        - Inability to perform adequately in school (including specialized setting) due to disruptive or aggressive behavior
        - Inability to communicate to get needs met
        - High levels of family conflict with parents struggling to parent member without highly trained ABA intervention.
        - High levels of conflict when in the community where the parents are unable to be within the community due to the severity of the member's behaviors or needs.

4. Treatment plans are submitted and should not be a template or generic to a particular program are not acceptable. The treatment plan should be specific to the specifics to the member's presentation and include **ALL** the following:

a. Treatment plans address all biopsychosocial needs that prevent the member from participating in developmentally and cognitively appropriate activities in home, school, or community settings.
b. Treatment for ABA should include coordination of care with other providers and community-based resources that the member is receiving or will be receiving. **All** the below should be met in relation to coordinator of care:
    - Treatment plans should outline all school or other community resources available to the patient. The treatment plan should provide evidence that the requested services are not redundant to other services being provided or will be provided (this might include school IEP or 504 plans, speech therapy, outpatient mental health therapy, etc.).
    - Coordination of care must take place between the community provider and the ABA provider, not through the parents.
    - If coordination of care was not achieved due to lack of response from providers/ resources, there is documented at least 3 attempts to coordinate.
c. Treatment plan includes explicit and measurable recovery goals that will define patient improvement, with regular assessment that progress toward goals is occurring or that condition would deteriorate in absence of continued applied behavioral analysis.
d. Treatment plan has a minimum of one assessment scale completed within the past 30 days from submission (if multiple assessments are completed, then those can also be submitted for review, however **only 1 is required**). These scales should be completed with the ABA provider and parents/guardians in an interview format, the parents/guardians should not complete on their own without professional support. The acceptable minimum assessment to send are the following and ordered in KP CO preference:
    - Vineland Adaptive Behavior Scales
    - Verbal Behavior Milestones Assessment and Placement Program (VB-MAPP)
    - Adaptive Behavior Assessment System Third Ed (ABAS-3)
    - ASEBA, Behavior Assessment System for Children, Third Ed. (BASC-3), Gilliam Autism Rating Scale
    - Assessment of Basic Language and Learning Skills (ABLLS), Achenbach System of Empirically Based Assessment (ASEBA)
e. Treatment plan engages family, caregivers, and other people impacted by and in position to impact member's behavior. There should be a focus on parent training as ABA is not a lifelong treatment of care and parents will need to be able to support their child once ABA services are no longer in the home.
    - The treatment plan must include detailed description of interventions with parents to support their active participation in ABA treatment, which should include a plan for how these interventions will be shifted to the parents once ABA treatment is no longer provided.
    - Parenting or caregiving training hours should be up to 3 hours a week. If parents are unable to complete this request, then there should be documented evidence as to what is hindering the guardian's/parent's capacity for attending this number of hours.

f. Recommended treatment intensity (i.e., number of hours per week) and duration (i.e., length of service intervention) is individualized and designed to meet the needs of patient. The treatment intensity should be attainable within the weekly constraints of the additional services being provided (things to take into consideration are school schedule, alternative therapy services, family, and leisure time, etc.) See below Coverage for Treatment planning hours and treatment hours policy for additional details.
g. Treatment plans are adjusted as is clinically appropriate when there is a change in presentation.

5. Situation and expectations are appropriate for ABA as indicated by **ALL** the following:
    a. Patient is expected to adequately participate in and respond as planned to proposed treatment
    b. Recommended treatment is necessary and not appropriate for less intensive care (e.g., patient behavior, symptoms, or risk is inappropriate for routine outpatient office care).
    c. Treatment is to be administered in setting (e.g., home vs specialized center) and by team (e.g., multidisciplinary) that is specifically designed and compatible with patient's needs and abilities.
    d. Targeted symptoms, behaviors, and functional impairments related to underlying behavioral health disorder have been identified as appropriate for applied behavioral analysis.

Coverage for treatment planning hours and treatment hours policy:

1. Assessments. The number of units for assessments are based on medical necessity criteria.
    a. The development of the individualized treatment plan does include time to do baseline assessments, review of past treatment (including IEPs) and development of a plan that includes parent training and coordination with other treatment providers. Six (6) to eight (8) hours for initial assessment and treatment plan development is sufficient. Three (3) to six (6) hours for continued assessments and treatment plan development every six (6) months is sufficient.
    b. Kaiser CO prefers to have ABA providers start ABA treatment immediately after initial assessments. KP CO does not want a delay in treatment for extended or additional assessments. It is strongly recommended that treatment start to build rapport with the member and family where then any ongoing assessments and probes can continue as treatment progresses. In ABA treatment, assessments are an ongoing component of the field and moving to treatment does not mean that assessments for new goals, objectives, targets, etc. do not stop occurring. KP CO will need strong substantial clinical evidence for additional requests for assessment hours where the treatment hours will not be sufficient to complete the ongoing assessments and probes.
    c. The ABA Assessment and Treatment Codes Conversion Table (link here) are the appropriate codes to be billing for assessments and treatment planning. Additional codes outside the typical ABA codes might not be approved.

- 97151: Behavior identification assessment administered by a QHP. Units are in 15-minute increments
    - Initial assessments and treatment plan development will be automatically authorized for 32 units (8 hours). This will be auto approved by KP CO developmental pediatric team when there is supporting evaluations recommending ABA therapy by a qualified practitioner. Three (3) hours (or 12 units of code 97151) for continued assessments and treatment plan development every six (6) months is sufficient. Any additional requests above the max threshold of 12 units of 97151 for six (6) months will require substantial clinical evidence that additional hours are necessary to a max of six (6) hours (or 24 units of code 97151).
    - This code can include face to face assessments with the member as well as indirect time reviewing records, scoring, and interpreting assessments, and writing the treatment plan. This is the only code that allows for non-face to face time. The QHP *must* conduct both activities for this service.
    - The day-to-day assessments of the QHP are bundled into the treatment codes and should not be requested to report those indirect services.

- 97152: Behavior identification supporting assessment administered by a Registered Behavioral Technician (RBT) under direction of physician/ QHP, face to face with patient. Units are in 15-minute increments.
    - KP CO rarely approves this code and should be used for very severe cases and substantial clinical evidence should be provided to determine medical necessity. We would need to understand what specifically the Registered Behavioral Technician (RBT) will be completing and why three (3) to six (6) hours (or 12 to 24 units) of code 97151 is not sufficient to be completed by the QHP. Remember QHP hours are bundled into the requesting units of this code.
    - This code is only for reporting supplemental assessments conducted by the Registered Behavioral Technician (RBT) that the QHP determines are needed to develop the treatment plans. The work of the QHP is bundled into the value of this code and should not be reported separately.

- 0362T: Behavior identification supporting assessment for severe behaviors administered by a QHP who is on-site, with the assistance of two or more Registered Behavioral Technicians (RBT), for a patient who exhibits destructive behavior, completed in an environment that is customized to a patient's behavior. Units are in 15-minute increments:
    - This code is for very severe and dangerous behaviors where multiple Registered Behavioral Technicians (RBT) and the QHP available on site is required. KP CO very rarely approves this code and if requested it will require submission of significant clinical evidence to substantiate the medical necessity criteria for this code.

2. Direct Treatment. The amount of direct treatment is based on medical necessity criteria.
    a. Comprehensive ABA for patients with ASD who are 1 to 12 years of age and require a program designed to address multiple areas of behavioral and functional impairment in a coordinated manner. Patients with ASD who are 1 to 12 years of age must be appropriate for comprehensive ABA whereas (1) Residual core ASD symptoms are still present despite past treatments or (2) the member lacks significant progress toward treatment goals despite past treatments or (3) focal deficits are present (e.g., isolated impairment in communication) that are appropriate for targeted behavioral intervention in patients who are not enrolled in comprehensive ABA treatment program.
    b. Focused ABA for those members with ASD who are 13 years of age or older and have focal deficits (e.g., isolated impairment in verbal communications) or when if the member is 12 or younger and has primary difficulty in one targeted area, then fewer hours for focused ABA are appropriate.
    c. Direct treatment intensity should be based on other services and schooling the member is receiving.
        - General guidelines are
            - if member is attending full days of school/preschool or early intervention
            - program direct ABA treatment should be up to 15 hours a week
            - if member is attending half days of school/preschool/ early intervention program direct ABA treatment should be up to 25 hours a week
            - If member is not enrolled in school/preschool/early intervention program, the member must be less than 6 years old and direct ABA treatment should be up to 30 hours a week.
        - As noted in research, early intervention programs, for children typically under the age of six might be appropriate for up to 25 hours a week and can last up to 12 weeks to 3 years. In the unusual case of very acute and/or unsafe patient behavior, up to 40 hours/week of treatment may be authorized.
            - If greater than 25 hours a week of treatment is being requested, please provide clinical rationale as to why this amount is being requested, the estimated time frame that this higher hour dosage will be provided, and the estimated plan to decrease the number of hours of ABA to allow other services and schooling to be resumed.

        - The KPCO Utilization Reviewer has the clinical judgement to request that the timeframe in between reviews be reduced from 6 months to 3 months due to the acuity of this member's presentation and the higher number of hours being requested.
            - The rationale for requesting such quick turnaround time for reviews is to ensure that the recommended treatment dosage appears to be improving the concerning behaviors and/or allow the treatment team to adjust, if necessary, changes need to be made to the treatment plan (i.e., if the hours can be reduced as the member made improvements with higher dosages or if the hours need to be increased as the member is regressing)

d. The ABA Assessment and Treatment Codes Conversion Table (link here) are the appropriate codes to be billing for direct treatment hours
    - Individual hours
    - 97153 Adaptive behavior treatment by protocol administered by a Registered Behavioral Technician (RBT) under the direction of QHP, Units are in 15-minute increments.
        - Please be sure to follow all above guidelines and policies in the above section C.
        - If a QHP is acting in place of the Registered Behavioral Technician (RBT), please provide clinical documented evidence as to why the QHP is being used vs a Registered Behavioral Technician (RBT).
        - Both 97153 and 97155 can be billed concurrently if both descriptors of both codes are accurate.
        - If the QHP is providing service hours, then 97153 and 97155 should not be provided concurrently.

    - 97155 Adaptive behavior treatment with protocol modification, administered by QHP, may be used for Direction of a Registered Behavioral Technician (RBT), face-to-face with one patient. Units are in 15-minute increments.
        - This code should be used when the QHP joins the Registered Behavioral Technician (RBT) and the member during a treatment session to modify treatment protocols. When the QHP is providing supervision to the Registered Behavioral Technician (RBT) with the member present, then 97153 can be billed concurrently. The modifications that might be made can include but not limited to (1) adjustments to specific components of a protocol, (2) observations to determine if the protocol is functioning effectively for the member (3) direction of a Registered Behavioral Technician (RBT) while the Registered Behavioral Technician (RBT) is delivering the service to the member to insure the procedures are being implemented correctly (4) QHP implementation of the protocol with the member to determine if changes are needed to improve progress or test a modified protocol.
        - When writing up the modified protocols, these are indirect services that are not reported separately and is bundled into 97155 for payment.
        - 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 documented clinical information as to why this is being requested outside the industry accepted standards.

    - 0373T Adaptive behavior treatment with protocol modification implemented by physician/QHP who is on-site with the assistance of two or more Registered Behavioral Technicians (RBT) for severe maladaptive behaviors. Units are in 15-minute increments

- This code is for very severe and dangerous behaviors where multiple Registered Behavioral Technicians (RBT) and the QHP available on site is required. KP CO very rarely approves this code and if requested it will require submission of significant clinical evidence to substantiate the medical necessity criteria for this code.
- Do not request for each Registered Behavioral Technician's (RBT) time individually. Only report the total time of one Registered Behavioral Technician (RBT) (i.e.: if three Registered Behavioral Technicians (RBT) are needed for a 3-hour session, report 12 units of 0373T).
- 0373T cannot be billed concurrently with 97155 if the QHP is directing the Registered Behavioral Technicians (RBT) during the session. These are indirect services and are bundled with this code.

- Group Hours
- 97154 Group adaptive behavior treatment by protocol by a Registered Behavioral Technician (RBT) under the direction of QHP, face-to-face with two or more patients. Units are in 15-minute increments
  - The provider is to submit documentation to outline the treatment plan on what groups they will target and the benefits to these groups on the member's presentation, just providing goals and targets is not sufficient.
  - A group consists of at least two (2) patients but no more than eight (8). Each patient attending the group session can be billed using this code.
  - Code 97154 and 97159 should not be billed concurrently, the 97158 code is intended to be used for QHP led group sessions only.
  - 97154 and 97155 can be billed concurrently if both code descriptors are met.
  - If the QHP is providing the 97154 hours, then 97155 should not be billed concurrently.

- 97158 Group adaptive behavior treatment with protocol modification by physician/QHP, face-to-face with two or more patients. Units are in 15-minute increments.
  - A group consists of at least two (2) patients but no more than eight (8). Each patient attending the group session can be billed using this code.
  - This code is intended to report for QHP led group sessions only and should not be billed with 97154 concurrently.
  - Protocol modifications includes but not limited to (1) adjustments to specific components of a protocol (2) observations to determine if the protocol is functioning effectively (3) active direction of a Registered Behavioral Technician (RBT) while the Registered Behavioral Technician (RBT) delivers the service to a patient to ensure that protocols are being administer correctly (4) QHP implements the protocol with the patient to determine if changes are needed.

- Modifying written protocols is an indirect service that is not reported separately but bundled with 97158.

- Family Training:
- 97156 Family adaptive behavior treatment guidance, administered by physician or other qualified healthcare professional (with or without the patient present), face to-face with guardian(s)/caregiver(s), each 15 minutes
  - If the family is receiving services with the QHP in another room, while the member is also receiving treatment with the Registered Behavioral Technician (RBT), 97156 can be billed with other service codes as these are separate and distinct services delivered to different members of the family by different providers.
  - Parenting or caregiving training hours should be up to 3 hours a week. If parents are unable to complete this request, then there should be documented evidence as to what is hindering the parent's capacity for attending this number of hours and any additional information on how the parents are going to

- 97157 Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified healthcare professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes.
  a. This code is not to be billed for every attendee in the group session, this code is to be used for the set of guardians/caregivers present in the group sessions. (i.e.: if three (3) parents attend the group session, then report the code for each set).

CRITERIA FOR CONTINUED CARE

For ongoing services to be authorized, the following must be met:

1. The above criteria for admission is met.
2. There is a signed behavioral therapy treatment plan that clearly outlines specific and measurable goals of the treatment plan.
   a. A description of how the direct treatment hours and supervision hours will be delivered at a sufficient intensity to achieve treatment plan goals.
   b. ABA delivery requires the support of family or caregivers. Evaluation should include assessment for caregiver stressors (e.g., marital discord) or other parental or environmental dysregulation that may impact treatment and provide support and resources to address any limitations.
   c. Treatment plan engages family, caregivers, and other people impacted by and in position to affect patient behavior, as appropriate.
   d. The level of caregiver training and support and how this support will be delivered in a manner individualized to the patient and family to ensure skills transfer to the caregiver.

- A plan of evaluation for measurable impact on the patient's behavior or skills.

e. Meaningful, measurable, functional improvement changes, or documentation of significant interfering events (e.g., serious physical illness, major family disruption, change of residence), if applicable. For changes to be meaningful, they must meet **ALL** the following: These assessments must be completed every year.

- Confirmed through data, including norm-referenced evidenced-based tools (e.g., most current edition of Adaptive Behavior Assessment System [ABAS-3] or Vineland Adaptive Behavior Scales [VABS-3])
  - Documented in charts and/or graphs
  - Durable over time beyond the end of the actual treatment session

f. A detailed plan to address challenges encountered during the previous authorized services, if applicable.

3. In addition, documentation is requested about other therapy services, including behavioral therapy services that have been provided or considered for the patient as appropriate. Please provide responses to all the following questions, with an explanation:
   a. Have less intrusive or less intensive behavioral interventions been provided or considered?
   b. Have other therapy services such as occupational therapy, physical therapy, or speech therapy been provided or considered?

Criteria for Telehealth Services for ABA

Situation	**Background**
• Specific components of Applied Behavior Analysis (ABA) are approved for telehealth delivery during the pandemic • Pandemic learnings indicate that telehealth has been an effective care delivery modality for these components, helping some families access effective and medically-necessary care who otherwise would not have been able to (due to, for example, geographical barriers) • Other KP regions (e.g., KP Washington, KP NW) are strongly considering extending approval for telehealth delivery indefinitely	• Authorized components of ABA approved for telehealth during the pandemic are 97155 (for direction/supervision of the RBT); 97156 and 97157 (family adaptive behavior treatment guidance) and 97151 (behavior identification assessment, initial or reassessment, administered by a QHP) • Services not authorized for telehealth delivery are 0373T, 97153, 97154, 97158, 97152, and 0362T
Assessment	**Recommendations for Next Steps**
• Extending approval for telehealth delivery of these specific ABA components will allow access to medically-indicated services for a maximum number of families • Assessment to determine the clinical value and use of telehealth for each client should continue to be completed by the Developmental Pediatrics and Autism team	• The Developmental Pediatrics and Autism team unanimously and strongly recommends the indefinite extension of approval for telehealth-delivery for select components of ABA treatment

DISCHARGE / EXCLUSION CRITERIA

The basis for denial of services is based on medical necessity.

1. Provisional diagnosis of ASD is not considered medical ASD diagnosis. Provisional diagnosis must be confirmed prior to start of ABA treatment and must meet the criteria above admission criteria.
2. ABA services are not meant to be lifelong treatment services. Slowly ABA services should be tapered down in intensity to eventually to transferred to parents/caregivers to implement. According to research, higher intensity of early intervention services (such as 25 hours plus) are to be at a max duration of 3 years then to taper down in intensity of services.
3. The member fails to respond to ABA services, even after encountering different ABA techniques and modifications with adequate duration of 2 years.
4. There are no meaningful, measurable, functional improvement changes, or progress has plateaued, without documentation of significant interfering events (e.g., serious physical illness, major family disruption, change of residence). The member does not exhibit progress towards goals for two or more successive authorization periods whereas continued care would be provided more for the convenience of the child and/or caregivers and considered custodial in nature. For changes to be meaningful, they must be all the following:
    a. Confirmed through norm-referenced evidenced-based tools e.g., most current edition of Adaptive Behavior Assessment System (ABAS-3) or Vineland Adaptive Behavior Scales (VABS-3)
    b. Confirmed through data
    c. Documented in charts and graphs
    d. Durable over time beyond the end of the actual treatment session
    e. Generalizable outside of the treatment setting to the patient's residence and the larger community within which the patient resides
5. The patient has achieved adequate stabilization of the challenging behavior and less-intensive modes of therapy are appropriate.
6. The patient demonstrates an inability to maintain long-term gains from the proposed plan of treatment.
7. Noncompliance (e.g., failure to keep appointments, caregiver fails to actively participate in treatment session, caregiver consistently fails to attend scheduled caregiver training sessions.)
    a. Parents have not been active participants in ABA treatment despite multiple attempts from ABA providers to engage the parents or caregivers in treatment.
8. Treatment is making symptoms persistently worse.
9. Services that are primarily respite, daycare, or educational in nature and are not used to reimburse a parent for participating in the treatment program.
10. Services that are duplicative services and equal to the medically necessary frequency and duration under an Individualized Family Service Plan (IFSP) or an Individualized Educational Program (IEP), as required under the federal Individuals with Disabilities Education Act (IDEA)
11. Custodial care. "Custodial care" is defined as any type of care where the primary purpose of the type of care provided is to attend to the patient's daily living activities which do not entail or require the continuing attention of trained medical or paramedical personnel (such as maintaining personal hygiene, safety, and independent living). For example, a professional attending a patient's summer camp program to ensure his/her safety would be considered custodial. The following services are considered custodial in nature (this list is not exhaustive):
    a. Autism Camps, Wilderness Camps, or other camps

b. Resorts or spas
c. Equine or Hippo-therapy
d. Primarily educational or vocational services or related to academic or work performance are considered not medically necessary
e. Recreational therapy
f. Respite care, custodial care, or safety monitoring services
g. School-based services
h. Life coaching
i. Treatment that is unproven /investigational

12. Services rendered by a parent, legal guardian, or legally responsible person.

Alternatives to Procedure

- Alternatives or adjunctive interventions:
  - Pharmacotherapy (e.g., atypical antipsychotics to treat aggression, or stimulant therapy for comorbid ADHD symptoms)(11)(15)(42)
  - Habilitative therapies including speech therapy, occupational therapy, and physical therapy
  - Cognitive behavioral therapy(43)(44)
  - Social skills training.
  - Mental health support services.
  - Therapeutic behavioral on-site services.

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

Sub department(s): Utilization Management Medical Directors	Last Review: 01.2023 Next Review: 01.2024 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.

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Utilization Management Department
KPCO Criteria for Skilled Therapies for Autism

Sub department(s): Utilization Management Medical Directors	Last Review: 10.2023 Next Review: 10.2024 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 rehabilitative 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.

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."
    b. If the patient does not meet Homebound criteria therapies may be approved but a specific note of 'not homebound' must be made in the approval note and Hold Code **CLH08** must be applied to the referral.
        i. This will make the family liable for usual therapy cost-share.
        ii. Since this is an exception to the home health rules, OT may be approved as a stand-alone service, when medically necessary.

5. The request is NOT for a non-covered service:
    a. Treatment for developmental disorder, developmental disability, or learning disability separate from the ASD is not covered.
    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).

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RESOURCE STEWARDSHIP
KPCO Criteria for Bariatric Surgery – Commercial Members

Sub department(s): Utilization Management MD	Last Review: 06.2023 Next Review: 06.2024 Approved by: Swan Davis, DO, Utilization Management Director

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.

* If a patient has a qualifying BMI at the time the referral was placed, the patient should still qualify for surgery even if weight loss occurs during the pre-operative period. The BMI and co-morbidities immediately prior to the referral for surgery will be used to assess eligibility for surgery. For qualifying patients, the referral for surgery will be valid for one year from the date it was placed.
The results of the pre-operative mental health evaluation will be valid for 6 months. The evaluating psychologist/therapist has the option to specify that the evaluation is valid for 12 months in low-risk individuals.

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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.

* If a patient has a qualifying BMI at the time the referral was placed, the patient should still qualify for surgery even if weight loss occurs during the pre-operative period. The BMI and co-morbidities immediately prior to the referral for surgery will be used to assess eligibility for surgery. For qualifying patients, the referral for surgery will be valid for one year from the date it was placed.

The results of the pre-operative mental health evaluation will be valid for 6 months. The evaluating psychologist/therapist has the option to specify that the evaluation is valid for 12 months in low-risk individuals.

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 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.

* If a patient has a qualifying BMI at the time the referral was placed, the patient should still qualify for surgery even if weight loss occurs during the pre-operative period. The BMI and co-morbidities immediately prior to the referral for surgery will be used to assess eligibility for surgery. For qualifying patients, the referral for surgery will be valid for one year from the date it was placed.

The results of the pre-operative mental health evaluation will be valid for 6 months. The evaluating psychologist/therapist has the option to specify that the evaluation is valid for 12 months in low-risk individuals.

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RESOURCE STEWARDSHIP
KPCO Criteria for Neuropsychological Testing

Sub department(s): Utilization Management MD	Last Review: 08.2023 Next Review: 08.2024 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)

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RESOURCE STEWARDSHIP
KPCO Criteria for Neuropsychological Testing for Children

Sub department(s): Utilization Management MD	Last Review: 08.2023 Next Review: 08.2024 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

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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:

KAISER PERMANENTE®

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

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 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.

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Utilization Management Department
KPCO Criteria for Hospital Grade Breast Pump Use

Sub department(s): Utilization Management Medical Directors	Last Review: 07.2023 Next Review: 07.2024 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.

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RESOURCE STEWARDSHIP
KPCO Criteria for Breast Reconstruction after Breast Cancer Surgery

Sub department(s): Utilization Management MD	Last Review: 04.2022 Next Review: 04.2023 Approved by: KPCO UM 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 of the following are met:

1. The patient has had a unilateral or bilateral mastectomy and ANY of the following are met:
    - *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.*
    - *Lumpectomies large enough to create a 'significant' deformity are covered 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.
        ii. *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. Use of 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,
      v. Asymmetry between breasts that is clinically significant,
      vi. Infection,
      vii. Deformity of the reconstructed breast(s) such that repair is indicated.

   Implants are not expected to last indefinitely, replacement 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. Uncontrolled diabetes, with the last A1C measurement >8.0.
   d. Any other contraindication to surgical anesthesia.
3. Augmentation before mastectomy as part of an approach to breast reconstruction 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].

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Utilization Management Department
KPCO Criteria for COVID-19 Monoclonal Antibody Reviews

Sub department(s): Utilization Management Medical Directors	Last Review: 4.2022 Next Review: 4.2023 Approved by: Cindy Hobbs-Huerta, RN, MS, UM Director; John Clark, MD, UM Regional Program Director

Title:
KPCO Criteria for COVID-19 Monoclonal Antibody Reviews

This guideline was developed to support clinician and utilization review teams about appropriate use of COVID-19 Monoclonal Antibody treatments. 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 COVID-19 Monoclonal Antibody Reviews.

COVID-19 Monoclonal Antibody treatments may be considered if ALL of the following (1-5) are met:

1. Patient has a positive COVID-19 PCR or antigen test within 10 days of the date of the request for treatment.
2. Patient's symptoms started less than 10 days from the date of the MAB infusion.
3. Patient has not been hospitalized (inpatient or overnight/observation stay) for any reason in the 10 days prior to the request and is not currently hospitalized or in an outpatient / observation status.
4. Patient does not have a new oxygen requirement or increased Oxygen requirement, if on continuous oxygen therapy.
5. Patient is age >/= 12 AND > 88 lbs.
6. Patient has one or more of the following risk factors:
    a. Age >/= 65
    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).

KAISER PERMANENTE®

Utilization Management Department
KPCO Criteria for Adolescent Bariatric Surgery

Sub department(s): Utilization Management Medical Directors	Last Review: 07.2023 Next Review: 07.2024 Approved by: KPCO UM 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)
2) Body mass index is greater than or equal to 40 kg/m2 or 140% of 95%ile

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3) Patient has been unsuccessful with non-operative strategies for weight loss, as shown by ALL the following:

   a) The patient has made a diligent effort to achieve healthy body weight with such efforts described in the medical record and certified by the operating surgeon.

   b) 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

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RESOURCE STEWARDSHIP
KPCO Criteria for Clinical Trial Coverage – Commercial Members

Sub department(s): Utilization Management MD	Last Review: 12.2021 Next Review: 12.2022 Approved by: Cindy Hobbs-Huerta RN, MSN, UM Director and John Clark, MD, Regional Program Director; Julie Ley, MD, UM Clinical Trials Lead

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 quired 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 National Clinical Trials title and identifier number is listed for the specific clinical trial for which the patient might qualify.
4. 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.
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.

Clinical trial services, including initial evaluation for a clinical trial, are not covered for Medicare Advantage beneficiaries because Medicare Fee for Service (FFS, "Original Medicare") is responsible for all payments related to clinical trials.

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RESOURCE STEWARDSHIP
KPCO Criteria for

Sub department(s): Utilization Management MD	Last Review: 06.2023 Next Review: 06.2024 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.

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RESOURCE STEWARDSHIP
KPCO Criteria for Injectable Calcimimetic Medications

Sub department(s): Utilization Management MD	Last Review: 09.2023 Next Review: 09.2024 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

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

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Utilization Management Department
KPCO Criteria for Coverage of Early Intervention Services

Sub department(s): Utilization Management Medical Directors	Last Review: 10.2023 Next Review: 10.2024 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

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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.

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RESOURCE STEWARDSHIP

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

Sub department(s): Utilization Management MD	Last Review: 06.2023 Next Review: 06.2024 Approved by: Swan Davis, D.O., Utilization Management Medical Director

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 **1 or more** of the following:
i) Initial injection, as indicated by **ALL** 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

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References:

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

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Utilization Management Department
KPCO Criteria for Gender Affirming Body Contouring Procedures

Sub department(s): Utilization Management Medical Directors	Last Review: 01.2023 Next Review: 01.2024 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. The request is for surgery affecting soft tissues of abdomen, flanks, and/or hips, and
3. Single letter of referral from a qualified mental health professional, which contains all relevant WPATH required information; and
4. There is persistent, well-documented gender dysphoria per DSM-5 criteria for Gender Dysphoric Disorder in the medical record; 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 documented as reasonably well controlled; and
7. The patient has completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless medically contraindicated; and
8. Patient has a stable BMI <30 because weight loss affects body fat distribution in a meaningful way, and
9. The request is not for alterations to the bony skeleton, and

10. 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)

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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.

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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.

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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

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

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 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”

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RESOURCE STEWARDSHIP
KPCO Criteria for Genetic Testing Reviews

Sub department(s): Utilization Management MD	Last Review: 08.2023 Next Review: 08.2024 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Genetic Testing Reviews

This guideline was developed to support clinician and utilization review teams about appropriate use of genetic 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 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.

KAISER PERMANENTE®

Utilization Management Department
KPCO Criteria for Advanced Imaging for Prostate Cancer

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 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.

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Utilization Management Department
KPCO Criteria for Home Health Care Utilization

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 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.

Home Health Care Exclusions:

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"

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

Sub department(s): Utilization Management MD	Last Review: 07.2023 Next Review: 07.2023 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

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Utilization Management Department
KPCO Criteria for Hypoglossal Nerve Stimulation Surgery

Sub department(s): Utilization Management Medical Directors	Last Review: 07.2023 Next Review: 07.2024 Approved by: KPCO UM 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.

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Utilization Management Department
KPCO Criteria for Female Infertility Referrals

Sub department(s): Utilization Management QRC and Medical Directors	Last Review: 09.2023 Next Review: 92.2024 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 their 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 their 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. Patient is over age 38 and is pre-menopausal.
    b. Patient is over age 35, less than age 38, and has attempted pregnancy for more than 6 months with unprotected intercourse.
        i. A miscarriage does not re-start the 6-month period of time, per ACOG guidelines.
    c. Patient is under age 35 and ANY of these is true:
        i. Has attempted pregnancy for more than 12 months with unprotected intercourse.
            1. A miscarriage does not re-start the 6-month period of time, per ACOG guidelines.
        ii. Anovulatory infertility (including PCOS) not responsive to oral agents, including use of clomid or letrozole for at least 3 cycles OR failure to conceive after 6 months with unprotected intercourse.
            1. A miscarriage does not re-start the 6-month period of time, per ACOG guidelines.
        iii. Documented family history of early menopause, defined as spontaneous cessation of menstrual cycles before the age of 40.
        iv. Documented Tubal Factor infertility other than by a voluntary sterilization procedure, as shown by an abnormal hysterosalpingogram (HSG).
        v. 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
        vi. Patient a single ovary, or a history of ovarian surgery, chemotherapy, or pelvic radiation therapy.
    d. Patient has functioning female reproductive anatomy (i.e. is capable of carrying a pregnancy) AND is in a same-sex relationship or is unpartnered.
    e. Abnormal semen analysis in the male partner, other than due to voluntary sterilization, if pregnancy is being sought through use of a male partner.

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Utilization Management Department
KPCO Criteria for Male Infertility Referrals

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 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 scrotal ultrasound has been completed and no reversible causes of infertility have been found.
4. A semen analysis has been completed.
5. 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.

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RESOURCE STEWARDSHIP
KPCO Criteria for Iron Infusion Therapy

Sub department(s): Utilization Management MD	Last Review: 04.2022 Next Review: 04.2023 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Iron Infusion Therapy

This guideline was developed to support clinician and utilization review teams about appropriate use of Iron Infusion 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.

This guideline applies to Commercial and Medicare lines of business.

Criteria for Iron Infusion Therapy

Iron Infusion therapy may be appropriate if Items 1 -3 are met OR Item 4 or Item 5 is met:

1. The patient has a demonstrated iron deficiency as demonstrated by ONE OR MORE of the following:
    a. Low serum iron with elevated total iron binding capacity (TIBC), or
    b. Low serum ferritin, or
    c. Absence of hemosiderin granules in bone marrow, or
    d. Transferrin Saturation (TSAT) between 10 and 20% with normal or increased serum Ferritin, or
    e. Diagnosis of Iron Deficiency AND diagnosis of one or more of the following:
        i. Hemochromatosis
        ii. Hemosiderosis
        iii. Thalassemia (alpha or beta)
2. The patient has failed oral iron supplementation as demonstrated by ONE OR MORE of the following documented in the provider note:
    a. Intractable nausea, constipation, or GI distress.
    b. Documented allergic reaction to oral iron.
    c. Poor absorption as shown by lab testing that meets criteria 1.a.-d. after a trial of oral iron supplementation.
    d. Presence of malabsorptive diseases of the GI tract (e.g. Crohn's disease, Ulcerative Colitis, other condition which interferes with iron absorption).

   e. Inability of oral iron to provide sufficient replacement, as shown by lab testing that meets criteria 1.a.-d. after a trial of oral iron supplementation.
3. The patient has met appropriate stepped therapy requirements as shown by ANY of the following:
   a. Iron Dextran (INFeD, Dexferrum) and Iron Sucrose (Venofer) are first line therapy and may be approved without any further conditions.
   b. If the patient has a documented allergy to Iron Dextran or Iron Sucrose, then Ferric gluconate or Ferric carboxymaltose may be approved.
   c. If the patient has documented allergy to Iron Dextran or Iron Sucrose AND a documented allergy to either Ferric gluconate or Ferric carboxymaltose, then Ferumoxytol may be approved.
4. For CKD IIIb, IV, and V patients not on hemodialysis, up to 6 iron infusions may be approved if ALL of the following are met:
   a. Hemoglobin < 12.0
   b. Transferrin saturation (TIBC) < 25%
   c. Ferritin </= 500
   d. Labs above are done within the last year.
5. For Medicare patients, NCD 110.10 mandates coverage for Iron Sucrose (Venofer) or sodium ferric gluconate (Ferrlecit, Nulecit) for any patient on chronic hemodialysis who is also receiving erythropoietin therapy, regardless of blood iron test results.
   a. Patients receiving on chronic hemodialysis on EPO do not need to prove iron deficiency.

For SoCo Parkside Infusion: iron sucrose and iron dextran are the only available forms; please do not approve other forms of iron to PKS Infusion

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RESOURCE STEWARDSHIP
KPCO Criteria for LINX Magnetic Sphincter Augmentation

Sub department(s): Utilization Management MD	Last Review: 07.2023 Next Review: 07.2024 Approved by: KPCO UM 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

- KP SoCal IRB inclusion criteria, Dr Umer Chaudry, email communication 10/1/2019.

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UTILIZATION MANAGEMENT
KPCO Criteria for Intraoperative Neuromonitoring

Sub department(s): Utilization Management MD	Last Review: 06.2023 Next Review: 06.2024 Approved by: KPCO UM 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

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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
95861, 62, 63, 64, 66, 69, 70	EMG studies outside of cranial nerves

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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)

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RESOURCE STEWARDSHIP
KPCO Criteria for Evaluation of Orofacial Surgery Referrals

Sub department(s): Utilization Management Medical Directors	Last Review: 10.2023 Next Review: 10.2024 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 supports that there is a functional problem, and the functional issue has either been refractory to orthodontia or unlikely to respond to orthodontics alone.
    iv. If Sleep Apnea is present, must have documentation that CPAP has been tried and has failed to adequately address symptoms of Sleep Apnea.

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Utilization Management Department
KPCO Criteria for Plastic Surgery Procedures

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2022 Next Review: 04.2023 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.

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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: 06.2023 Next Review: 06.2024 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.

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RESOURCE STEWARDSHIP
KPCO Criteria for Sleep Studies (Polysomnogram)

Sub department(s): Utilization Management MD	Last Review: 04.2022 Next Review: 04.2023 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)

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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.)

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Utilization Management Department
KPCO Criteria for Speech Therapy

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

Title:
KPCO Criteria for Speech Therapy

This guideline was developed to support clinician and utilization review teams about appropriate use of Speech 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.

Criteria for Pediatric Speech Therapy

Pediatric Speech Therapy services may be considered if ALL (1-3) the following are met:

1. The child has a qualifying diagnosis for Speech Therapy, including ANY of these:
    a. Expressive or Receptive Language disorder
    b. Articulation disorder or Apraxia
    c. Disorders of Voice quality or resonance
    d. Stuttering
    e. Auditory processing disorder that affects language skills
    f. Feeding difficulties
    g. Social Communication Disorder diagnosis, or have a diagnosis associated with a pragmatic language delay, including Autism Spectrum Disorder, Fragile X Syndrome, or a related developmental or neurological disorder.
    h. Training for use of an Augmentative or Alternative Communication Device (AAC Therapy) when the child has an AAC device.
2. For Initial therapy the child has EITHER
    a. The child has a significant disorder speech as shown by 1.0 or more Standard Deviations below the mean on standardized testing, or
    b. A feeding problem that is impacting the child medically (i.e., failure to thrive, weight loss, failure to gain weight, weight below the 10%ile, frequent illnesses, nutritional deficiency) for which speech or occupational therapy is likely to improve. The Child must have a feeding evaluation by a qualified speech or occupational therapist before therapy can be approved.

3. For subsequent, re-certification periods, the child has shown any of the following:
    a. Good progress in therapy, as shown by 0.5 standard deviation improvement or more in standardized testing, or
    b. Cognitive testing shows cognitive scores are higher than language testing scores, and the child has made some improvement from prior standardized testing but less than one-half (0.5) standard deviation, or
    c. The gap between expressive language scores and receptive language scores is narrowing, or
    d. Documented progress in feeding therapy, with continued medical need based on review by the speech department.
        i. If no improvement on standardized testing: STOP – medical necessity denial. Failure to progress indicates this therapy is not effective for the child.
    e. The request is for a covered therapy for Autism Spectrum Disorder (ASD) and if the therapy is specific to treating the ASD:
        i. Evaluation and assessment by a speech therapist
        ii. Habilitative or Rehabilitative Care where there is a skilled component,
        iii. Maintenance therapy or long-term rehabilitative care when medically necessary to treat ASD.
        iv. There are no visit limits or age limits for maintenance or long-term therapies related to ASD; this is an exception to the limited duration requirement for other diagnoses.
        v. The services must be medically necessary for the treatment of the ASD.
        vi. The services must be part of a plan documented by someone with expertise in treating the ASD.

4. The following circumstances do not meet criteria for speech therapy:
    a. The child has only an Auditory Processing disorder in the absence of any significant receptive or expressive language deficit.
    b. The child has a disorder of Executive Functioning in the absence of any significant receptive or expressive language deficit.
    c. Tongue thrust or other myofunctional therapy.
    d. Evaluation and/or treatment of academic and/or learning problems
    e. Child has significant behavioral or attention problems such that they are unable to meaningfully participate in Speech Therapy.
    f. Maintenance therapy when improvements are no longer being made
    g. Language therapy when the child's language skills are commensurate with their cognitive skills.

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Criteria for Adult Speech Therapy services

1. Adult Speech Therapy services will be considered if
    a. The adult has a NEW onset of a speech/language disorder related to an acute medical condition, which may include some of the following examples: CVA, brain tumor, any other neurological diseases, and oral/laryngeal cancers
2. The following circumstances do not meet criteria for speech therapy:
    a. Condition is long term/chronic and is not likely to be remediated in adulthood
    b. Stuttering, articulation differences, or any other diagnosis that began in childhood and has not changed

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Utilization Management Department
KPCO Criteria for Surgical Venue for Total Joint Arthroplasty

Sub department(s): Utilization Management Medical Directors	Last Review: 7.2023 Next Review: 7.2024 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Surgical Venue for Total Joint Arthroplasty

This guideline was developed to support clinician and utilization review teams about appropriate use of surgical venue for total joint arthroplasty. 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 Surgical Venue for Total Joint Arthroplasty, including knee, hip, and shoulder arthroplasties

Use of an Ambulatory Surgical Venue for total knee, total hip, or total shoulder arthroplasty for both Commercial and Medicare members is appropriate if ALL of the following are met:

- Unilateral, uncomplicated, primary hip, knee, or shoulder arthroplasty
    i. Ex: no other joint disease such as rheumatoid arthritis. No prior surgical intervention with hardware present. No recent joint infection.
- ASA 1 or 2 and approved by Anaesthesiologist on chart review
- Pre-operative Body Mass Index </= 37.5 kg/m^2
- Age < 75 years at time of surgery for hip or knee, and age < 80 years for shoulder.
- Pre-operative hemoglobin > 12 g/dL
- No history of seizure disorder
- Not currently under the care of a Gastroenterologist for any liver related diagnosis (no active liver disease)
- Preoperative GFR >60
- Diabetes: HgA1c <7

- Drinks less than 14 alcoholic beverages per week
- 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.
- Preoperative ambulatory status does not require the use of a walker or wheelchair
- No chronic (>6 months continuous) pre-operative opioid medication use or history of Opioid Substance Use Disorder
- No history of significant nausea with opiate use
    i. Exception: patients who have nausea with one type of opiate but have proven to tolerate others are OK
- Not immunocompromised or taking immunomodulatory medications
    i. Ex. Rheumatology or Gastroenterology patients on infusions, history of solid organ transplant, history of any type of Immunodeficiency disease.
- Patients are not currently classified as disabled or on SSD.

Hospital Inpatient (POS 21) venue for total knee, total hip, and total shoulder arthroplasties is appropriate for bilateral joint replacement.

Hospital Outpatient (POS 22) venue for total knee, total hip, and total shoulder arthroplasties is appropriate if NONE of the criteria above for ASC or Inpatient Status are met.

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Utilization Management Department
KPCO Criteria for Use of Teplizumab

Sub department(s): Utilization Management Medical Directors	Last Review: 01.2023 Next Review: 01.2024 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for Use of Teplizumab

This guideline was developed to support clinician and utilization review teams about appropriate use of **Use of Teplizumab** 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 interregional practice recommendations were developed and are endorsed by the Kaiser Permanente Interregional Clinician Workgroup for teplizumab. FDA approval of teplizumab-mzwv (Tzield) was based on one Phase 2, double-blind, placebo-controlled clinical trial that demonstrated a delay in the development of Stage 3 type 1 diabetes (T1D) in which patients with Stage 2 T1D treated with teplizumab had a median 25-month delay compared to placebo. While it appears to offer a promising treatment option to delay developing Stage 3 T1D, the trial only enrolled 76 patients and there is an unknown impact on long-term blood sugar control, risk of long-term malignancies, or diabetic ketoacidosis. Given the limited clinical trial data and lack of long-term safety data, exceedingly judicious prescribing and monitoring of therapy are warranted. The recommendations will be updated as needed to incorporate new evidence as it becomes available.

Criteria for Use of Teplizumab

Teplizumab may be considered if ALL of the following are met:

Recommend initiating if the following apply

• Age 8 to 45 years; and
• Have a first or second degree relative with T1D o If first degree, relative must be 8-45 years old (brother, sister, parent, or offspring)
o If second degree relative, must be between 8-20 years old (niece, nephew, aunt, uncle, grandchild, or cousin)

and
• Abnormal glucose tolerance by oral glucose tolerance test (OGTT) defined as fasting blood glucose >110mg/dL and <126 mg/dL OR 2-hour glucose ≥140 mg/dL and <200 mg/dL OR 30-, 60-, or 90-minute value on OGTT ≥200 mg/dL; and

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• Presence of at least two diabetes autoantibodies: glutamic acid decarboxylase 65 (GAD) autoantibody, zinc transporter 8 (ZnT8) autoantibody, islet cell autoantibody (ICA), insulin autoantibody (IAA), or insulinoma-associated antigen-2 (IA-2) autoantibody

Do not initiate if any of these apply

• On immunosuppressant including corticosteroids; or
• History of cardiovascular disease or coronary artery disease; or
• History of gestational diabetes; or
• Abnormal complete blood cell count (CBC) (lymphocyte count <1,000 lymphocytes/mcL, hemoglobin <10 g/dL, platelet count <150,000 platelets/mcL, absolute neutrophil count <1,500 neutrophils/mcL), liver enzymes (elevated alanine aminotransferase [ALT] or aspartate aminotransferase [AST] >2 times the upper limit of normal [ULN], or bilirubin >1.5 times ULN), or international normalized ratio (INR); or

• T1D that has been previously diagnosed or detected at baseline (fasting glucose ≥126 mg/dL or 2-hour glucose ≥200 mg/dL); or
• Positive purified protein derivative (PPD) test for tuberculosis infection; or
• Live virus vaccination within eight weeks of initiation; or
• Active serious infection or chronic active infection other than localized skin infections; or
• Past or current human immunodeficiency virus (HIV), Hepatitis B, or Hepatitis C infection; or
• Currently pregnant or breastfeeding (a lactating woman may interrupt breastfeeding and pump and discard breast milk during treatment and for 20 days after teplizumab administration to minimize drug exposure to a breastfed child); or
• Treatment in the past year of any monoclonal antibody; or
• Previous pancreatectomy and chronic pancreatitis; or
• Renal failure or chronic kidney disease; or
• Anemia; or
• Laboratory or clinical evidence of acute infection with Epstein-Barr virus (EBV) or cytomegalovirus (CMV)
• Caution in patients who have been treated with radiation for lymph diseases

• Within two weeks prior to initiation of therapy: o QuantiFERON (to test for tuberculosis)
o Fasting glucose

- o Liver enzyme tests
- o CBC with differential
- o Metabolic panel
- o Hepatitis B, Hepatitis C, and HIV panels
- o INR

• Pregnancy test within 24 hours, if applicable

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Utilization Management Department
KPCO Criteria for TPN, IPN, IDPN Requests

Sub department(s): Utilization Management Medical Directors	Last Review: 05.2023 Next Review: 05.2024 Approved: KPCO UM Committee

Title:
KPCO Criteria for TPN, IPN, IDPN Requests

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

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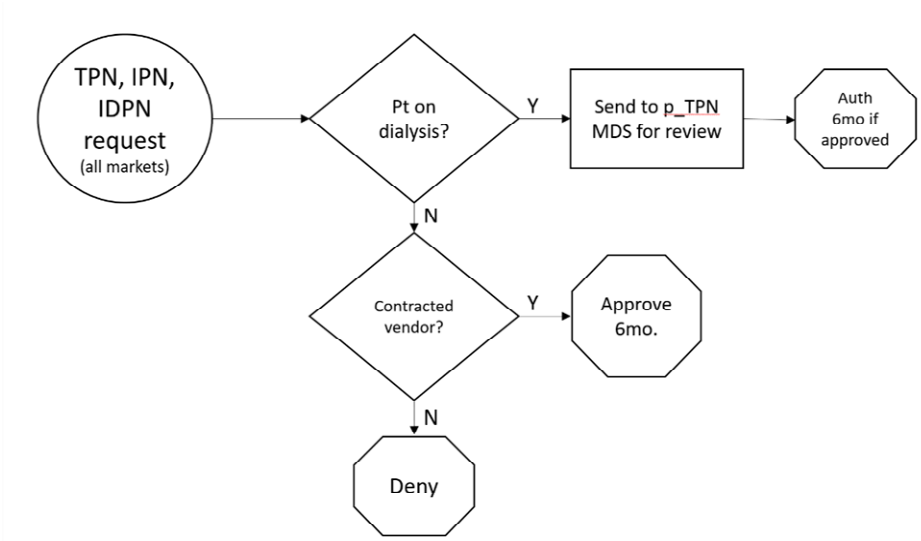

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Utilization Management Department
KPCO Criteria for Gender Affirming Facial Surgery

Sub department(s): Utilization Management Medical Directors	Last Review: 01.2023 Next Review: 01.2024 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. Age 18 years or older, or if under 18 on a case-by-case basis as determined by the Gender Health Medical Director; and

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

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

5. 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

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

7. BMI is less than 40.0

8. Patient is a non-smoker.

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Utilization Management Department
KPCO Criteria for CYP2D6 Pharmacogenomic Testing

Sub department(s): Utilization Management Medical Directors	Last Review: 04.2022 Next Review: 04.2023 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for

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

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

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

Sub department(s): Utilization Management Medical Directors	Last Review: 01.2022 Next Review: 01.2023 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 Omicron variant of COVID-19 represents at least 80% of the infections in the region, and
4. The patient weighs at least 3.5kg (7.7lbs; remdesivir is approved for children), and
5. 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).

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Utilization Management Department
KPCO Criteria for Upper Extremity Brace

Sub department(s): Utilization Management Medical Directors	Last Review: 07.2023 Next Review: 07.2024 Approved by: KPCO UM Committee

Title:
KPCO Criteria for Upper Extremity Brace

This guideline was developed to support clinician and utilization review teams about appropriate use of **Upper Extremity Brace**. 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 Upper Extremity Brace

Upper Extremity Brace may be considered if ANY of the following are met:

1. Up to six months after a covered injury of the extremity, or
    a. A “covered injury” is one where there is no issue of Third-Party Liability.
2. Up to one year after corrective or reconstructive surgery of the extremity, or
3. There is documentation of spasticity of the extremity with some degree of flexibility such that a dynamic splint is reasonably likely to provide some benefit for the patient.

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Utilization Management Department
KPCO Criteria for Left Atrial Appendage Closure

Sub department(s): Utilization Management Medical Directors	Last Review: 08.2023 Next Review: 08.2024 Approved by: KPCO Utilization Management Committee

Title:
KPCO Criteria for

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.