STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT - SQ	ORENCIA - SQ ORENCIA CLICKJECT - SQ		30289 41656 43389 43397	GPI-14 (6640001000D520) (6640001000E510) (6640001000E515) (6640001000E520)	

NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **125mg/mL syringe: #4mL per 28 days.**
   - **125mg/mL ClickJect: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Actemra (tocilizumab), Xeljanz (tofacitinib IR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
     - **125mg/mL syringe: #4mL per 28 days.**
     - **87.5mg/0.7mL syringe: #2.8mL per 28 days.**
     - **50mg/0.4mL syringe: #1.6mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 as requested with the following quantity limits:**
     - **125mg/mL syringe: #4mL per 28 days.**
     - **125mg/mL ClickJect: #4mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - SQ (Orencia - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful) to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Actemra (tocilizumab), Xeljanz IR (tofacitinib immediate release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

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ABATACEPT – SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You had a trial of or contraindication (harmful) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
4. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABATACEPT - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

     If yes, continue to #2.
     If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
     - **125mg/mL syringe: #4mL per 28 days.**
     - **125mg/mL ClickJect: #4mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Actemra (tocilizumab), Xeljanz (tofacitinib IR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
     - **125mg/mL syringe: #4mL per 28 days.**
     - **87.5mg/0.7mL syringe: #2.8mL per 28 days.**
     - **50mg/0.4mL syringe: #1.6mL per 28 days.**

     If no, continue to #4.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE**: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
     - **125mg/mL syringe: #4mL per 28 days.**
     - **125mg/mL ClickJect: #4mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - SQ (Orencia - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You meet ONE of the following:
      a. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Actemra (tocilizumab), Xeljanz IR (tofacitinib immediate release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

D. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You had a trial of or contraindication (harmful) to TWO of the following preferred medications: Taltz (ixekizumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia SQ.

REFERENCES

- Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 11/11
Client Approval: 07/23
P&T Approval: 04/23