



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APREMILAST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREMILAST	OTEZLA	40967		GPI-10 (6670001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. 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 given in consultation with a rheumatologist or dermatologist
 - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, enter approval(s) by GPID or GPI-14 as follows:

- If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND
- Approve for 6 months for #2 tablets per day

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, enter approval(s) by GPID or GPI-14 as follows:

- If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND
- Approve for 6 months for #2 tablets per day

APPROVAL TEXT: Renewal requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, continue to #3.

3. Does the patient have a diagnosis of Behçet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to **ONE** or more conservative treatments (e.g., colchicine, topical corticosteroid, oral corticosteroid, etc.)

If yes, enter approval(s) by GPID or GPI-14 as follows:

- If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND
- Approve for 6 months for #2 tablets per day

APPROVAL TEXT: Renewal requires that the patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers, etc.).

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)

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 **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
 2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
 3. Behçet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
- B. **If you have psoriatic arthritis (PsA), approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
 3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- C. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
 3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
 4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- D. **If you have Behçet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a rheumatologist (joint pain and inflammation doctor)
 3. You have previously tried ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, unless there is a medical reason why you cannot (contraindication)

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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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

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

If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**

If no, continue to #2.

2. Does the patient have moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**

If no, continue to #3.

3. Does the patient have Behçet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms **AND** meet the following criterion?

- The patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers, etc.)

If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**

If no, do not approve.

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 **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:

- A. You have psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches), moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales) or Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
- B. **If you have psoriatic arthritis (PsA), 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

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

- C. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
 1. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
- D. **If you have Behcet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
 1. You have achieved or maintained clinical benefit compared to baseline such as an improvement in pain scores, number of ulcers, etc.

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 Otezla.

REFERENCES

- Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

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P&T Approval: 01/20