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 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

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 per day.

If no, continue to #2.

- 2. Does the patient have a diagnosis of mild plaque psoriasis (PsO) 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 dermatologist
 - The patient had a trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) OR one conventional topical agent (e.g., PUVA, UVB, topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate])

If yes, continue to #3. If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

- 3. Does the patient meet **ONE** of the following criteria?
 - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
 - The patient has psoriasis covering 2% of body surface area (BSA)
 - The patient has a static Physician Global Assessment (sPGA) score of 2
 - The patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9

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 per day.

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

- 4. 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 in consultation with a dermatologist
 - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA, UVB, topical corticosteroids (e.g., betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, continue to #5. If no, continue to #6.

- 5. Does the patient meet **ONE** of the following criteria?
 - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
 - The patient has psoriasis covering 3% or more of body surface area (BSA)
 - The patient has psoriatic lesions affecting the hands, feet, face, or genital area

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 per day.

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)

- 6. Does the patient have a diagnosis of Behcet'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 in consultation with a rheumatologist
 - The patient had a trial of or contraindication to ONE or more conservative treatments (e.g., colchicine, topical corticosteroid, oral corticosteroid)

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 per day.

If no, do not approve.

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 (a type of skin and joint condition)
- 2. Plaque psoriasis (a type of skin condition)
- 3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. 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 for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. If you have mild plaque psoriasis, approval also requires:

- 1. You are 18 years of age or older
- 2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You had a trial of or contraindication to (harmful for) one conventional (standard) systemic (treatment that targets the entire body) agent (such as methotrexate, acitretin, cyclosporine) OR one conventional topical agent (such as Phototherapy Ultraviolet Light A [PUVA], Ultraviolet Light B [UVB], topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])

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APREMILAST

INITIAL CRITERIA (CONTINUED)

- 4. You meet ONE of the following:
 - a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
 - b. You have psoriasis covering 2 percent of body surface area (BSA)
 - c. You have a static Physician Global Assessment (Spga: a measure used to evaluate severity of your disease) score of 2
 - d. You have a Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of your disease) score of 2 to 9
- D. If you have moderate to severe plaque psoriasis, approval also requires:
 - 1. You are 18 years of age or older
 - 2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
 - You had a trial of or contraindication (harmful for) to ONE or more forms of conventional (standard) therapies, such as Phototherapy Ultraviolet Light A (PUVA), Ultraviolet Light B (UVB), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, cyclosporine
 - 4. You meet ONE of the following:
 - a. You were previously stable on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
 - b. You have psoriasis covering 3 percent or more of body surface area (BSA)
 - c. You have psoriatic lesions (rashes) affecting your hands, feet, face, or genital area
- E. If you have Behcet'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. 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 for) to ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid

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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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

APREMILAST

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 per day.** If no, continue to #2.

- 2. Does the patient have mild 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 OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline

If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.** If no, continue to #3.

- 3. 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 per day.** If no, continue to #4.

- 4. Does the patient have Behcet'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)

If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.** If no, do not approve. **DENIAL TEXT:** See the renewal denial text at the end of the guideline.

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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 **APREMILAST (Otezla)** requires the following rule(s) be met for renewal: A. You have ONE of the following diagnoses:

- 1. Psoriatic arthritis (a type of skin and joint condition)
- 2. Plaque psoriasis (a type of skin condition)
- 3. Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
- B. If you have psoriatic arthritis, renewal also requires:
 - 1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- C. If you have mild plaque psoriasis, renewal also requires:
 - You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of your disease) of at least 50 percent or more OR a decrease in static Physician Global Assessment (Spga: a measure used to evaluate severity of your disease) by at least a 2-point reduction from baseline
- D. If you have moderate to severe plaque psoriasis, renewal also requires:
 - 1. You achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: a measure used to evaluate severity of your disease) of at least 50 percent or more
- E. 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

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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RATIONALE

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

REFERENCES

• Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; December 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Commercial Effective: 07/01/23 Created: 04/14 Client Approval: 05/23

P&T Approval: 04/23