Pharmacy Drug Policy & Procedure

Policy Name:	Plaque Psoriasis Immunomodulator Therapies	Policy #:	2750P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of immunomodulators used in the treatment of Plaque Psoriasis (PsO) for new starts to therapy.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Cimzia, covered adalimumab biosimilars, Stelara, Tremfya, Otezla, Skyrizi, Taltz, Enbrel, Siliq, Cosentyx, Ilumya, or Sotyktu under the specialty benefit when the following criteria have been met.

Covered adalimumab biosimilars (as of 7/1/2024) include: Amjevita (72511040001, 72511040002, 55513039901, 555130479**, 555130481**, 555130482**), Hadlima (78206018701, 78206018401, 78206018601, and 78206018301), Adalimumab-adaz (61314032720 and 61314032764), and Adalimumab-adbm (005970545**, 00597055580, 00597056520, 005970575**, 00597058589, and 00597059520).

Criteria

1. Coverage Criteria of Preferred Products (Cimzia, covered adalimumab biosimilars, Enbrel, Otezla, Stelara IV or Sub-Q, Tremfya, Skyrizi)

1.1 Diagnosis of moderate to severe plaque psoriasis defined as more than 5 to 10% of body surface area affected, OR involvement of the face, palm, sole, or genitals, OR disease that is otherwise disabling

1.2 Ordered by a Dermatologist (skin doctor)

1.3 Age 18 years or older (age 6 years or older for Stelara/Otezla and age 4 years or older for Enbrel)

1.4 Documented failure, intolerance, or contraindication to ONE of the following:

- Phototherapy
- Traditional systemic therapy (methotrexate, cyclosporine, and acetretin)
- Topical therapy (such as topical steroids, tazarotene, tacrolimus)

2. Coverage Criteria of Non-Preferred Products with Single Step Edit (Taltz)

2.1 Diagnosis of moderate to severe plaque psoriasis defined as more than 5 to 10% of body surface area affected, OR involvement of the face, palm, sole, or genitals, OR disease that is otherwise disabling

2.2 Ordered by a Dermatologist (skin doctor)

2.3 Age 6 years or older

2.4 Documented failure, intolerance, or contraindication one of the following:

- Phototherapy
- Traditional systemic therapy (methotrexate, cyclosporine, and acetretin)
- Topical therapy (such as topical steroids, tazarotene, tacrolimus)

2.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to any ONE of the following:
- Cimzia
- Covered adalimumab biosimilars
- Enbrel
- Stelara
- Tremfya
- Skyrizi

3. Coverage Criteria of Non-Preferred Products with Triple Step Edit (Bimzelx)

3.1 Diagnosis of moderate to severe plaque psoriasis defined as more than 5 to 10% of body surface area affected, OR involvement of the face, palm, sole, or genitals, OR disease that is otherwise disabling

3.2 Ordered by a Dermatologist

3.3 Age 6 years or older

3.4 Documented failure or intolerance to ONE of the following:
- Phototherapy
- Traditional systemic therapy (methotrexate, cyclosporine, acetretin)
- Topical therapy (topical corticosteroids, vitamin D analogs, etc)

3.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to Taltz and any TWO of the following:
- Cimzia
- Enbrel
- Otezla
- Stelara
- Tremfya
- Skyrizi

4. Coverage Criteria of Non-Preferred Products with Quadruple Step Edit (Siliq, Cosentyx, Ilumya, Sotyku)

4.1 Diagnosis of moderate to severe plaque psoriasis defined as more than 5 to 10% of body surface area affected, OR involvement of the face, palm, sole, or genitals, OR disease that is otherwise disabling

4.2 Ordered by a Dermatologist (skin doctor)

4.3 Age 18 years or older (age 6 years or older for Cosentyx)

4.4 Documented failure, intolerance, or contraindication to one of the following:
- Phototherapy
- Traditional systemic therapy (methotrexate, cyclosporine, acetretin)
- Topical therapy (such as topical steroids, tazarotene, tacrolimus)

4.5 Documented failure to respond to a minimum 3 month trial, intolerance, or contraindication to Taltz and THREE of the following:
- Cimzia
- Covered adalimumab biosimilars
- Enbrel
- Stelara
- Tremfya
- Skyrizi

5. Exclusion Criteria

5.1 Allergic reaction to murine proteins or humanized monoclonal antibody
5.2 Inadequate response to initial or previous therapy with requested immunomodulator
5.3 Patients with active infections, latent tuberculosis, or symptomatic or deteriorating congestive heart failure
5.4 Off-label (non FDA Approved) dosing frequencies
5.5 Health Alliance Northwest does not cover more than one biologic immunomodulator at a time because of possible increased risk for infections and potential drug interactions
5.6 Only certain NDCs of adalimumab biosimilars will be considered for coverage, please reference statement of policy for covered NDCs

6. FDA Approved Dosages for Plaque Psoriasis

6.1 Cimzia: 400mg sub-q every other week; For patients ≤ 90kg, an initial dose of 400mg at weeks 0, 2, and 4, followed by 200mg sub-q every other week thereafter may be considered
6.2 Covered adalimumab biosimilars: 80mg sub-q as a single dose, followed by 40mg sub-q every other week beginning 1 week after initial dose
6.3 Stelara: ≤ 100kg: 45mg sub-q at weeks 0 and 4, and then every 12 weeks thereafter; > 100kg: 90mg sub- q at weeks 0 and 4, and then every 12 weeks thereafter
6.4 Tremfya: 100mg sub-q at weeks 0, 4, and then every 8 weeks thereafter
6.5 Otezla: Day 1 – 10mg po in the morning, Day 2 – 10mg po twice daily, Day 3 – 10mg po in the morning and 20mg po in the evening, Day 4 – 20mg po twice daily, Day 5 – 20mg po in the morning and 30mg po in the evening, then maintenance dose of 30mg po twice daily
6.6 Skyrizi: Two consecutive 75mg sub-q injections at weeks 0, 4, and then every 12 weeks thereafter
6.7 Taltz: 160mg sub-q once, followed by 80mg sub-q at weeks 2, 4, 6, 8, 10, and 12, and then 80mg sub-q every 4 weeks
6.8 Enbrel: 50mg sub-q twice weekly for 3 months, then 50mg sub-q once weekly
6.9 Siliq: 210mg sub-q at weeks 0, 1, and 2, followed by 210mg sub-q every 2 weeks
6.10 Cosentyx: 300mg sub-q once weekly at weeks 0, 1, 2, 3, and 4 followed by 300mg sub-q every 4 weeks
6.11 Ilumya: 100mg sub-q at weeks 0, 4, and then every 12 weeks thereafter
6.12 Sotyktu: 6mg by mouth once daily
6.13 Bimzelx: 320 mg sub-q once every 4 weeks for the first 16 weeks, and then every 8 weeks thereafter

7. Approval Period

7.1 Initial authorization will be placed for 12 months
7.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

CPT Codes	

HCPCS Codes	

References

1. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. Journal of the American Academy of Dermatology. Clinical Practice Guideline. 2020 July 29.
2. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. Journal of the American Academy of Dermatology. Clinical Practice Guideline. 2019 July 25: 81(3); 775-804.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal of the American Academy of Dermatology. Clinical Practice Guideline. 2020 Feb 28: 82(6); 1445-1486.
4. Menter A, Strober, BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. Clinical Practice Guideline. 2019 April 1: 80(4); 1029-1072.

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