Clinical Policy Title:	tildrakizumab-asmn
Policy Number:	RxA.736
Drug(s) Applied:	Ilumya®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Ilumya® is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tildrakizumab-asmn (Ilumya®)	Moderate-to-severe plaque psoriasis	Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 12 weeks; tildrakizumab should only be administered by a healthcare professional.	100 mg every 12 weeks

Dosage Forms

- Single-dose prefilled syringe: 100 mg/1 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque Psoriasis (PsO);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 18 years;

4. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;
5. Member meets both (a and b):
   a. Trial and failure of at least three (3) first line agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced;
      *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
   b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 100 mg/dose subcutaneously.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Plaque Psoriasis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 100 mg/dose subcutaneously.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
MTX: methotrexate
DMARDs: Disease-Modifying Antirheumatic Drugs
PsO: Plaque Psoriasis
PUVA: Psoralen plus ultraviolet A light

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin	25 or 50 mg orally once daily	50 mg/day
cyclosporine (Sandimmune®, Neoral®)	1 - 4 mg/kg/day orally divided twice daily	4 mg/kg/day
methotrexate	10 - 25 mg/week subcutaneously	30 mg/week
Biologic DMARDs		
Humira®	Initial dose: 80 mg Maintenance dose:	40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	40 mg subcutaneously every other week starting one week after initial dose	
Otezla®	Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orally in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Siliq®	Initial dose: 210 mg subcutaneously at weeks 0, 1, and 2 Maintenance dose: 210 mg subcutaneously every 2 weeks	210 mg every 2 weeks
Cimzia®	400 mg subcutaneously every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg subcutaneously at 0, 2 and 4 weeks, followed by 200 mg subcutaneously every other week may be considered.	400 mg every other week
Enbrel®	Adults: Initial dose: 50 mg subcutaneously twice weekly for 3 months (Starting doses of 25 mg or 50 mg per week are also shown to be efficacious) Maintenance dose: 50 mg subcutaneously once weekly Pediatrics: Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly	50 mg/week
Tremfya®	Initial dose: 100 mg subcutaneously at weeks 0 and 4 Maintenance dose: 100 mg subcutaneously every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	100 mg every 8 weeks
infliximab (Remicade®),	Initial dose:	5 mg/kg

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Renflexis®, Inflectra®, Avsola®	5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks	every 8 weeks
Taltz®	Adult Plaque Psoriasis: Recommended dose is 160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks Pediatric Plaque Psoriasis(age 6 years or older): For patients weighing greater than 50 kg:160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For patients weighing 25-50 kg: 80 mg subcutaneoulsy at Week 0, followed by 40 mg every 4 weeks. For patients weighing less than 25 kg:40 mg subcutaneously at Week 0, followed by 20 mg every 4 weeks	80 mg every 4 weeks
Skyrizi®	150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Cosentyx®	Adults:300 mg subcutaneously at weeks 0, 1, 2, 3, and 4, followed by 300 mg subcutaneously every 4 weeks. (for some patients, a dose of 150 mg may be acceptable) Pediatric Patients 6 years of age and older Weight < 50 kg : 75 mg at weeks 0,1,2,4 and 4 followed by dosing every 4 weeks Weight ≥ 50 kg: 150 mg at weeks 0,1,2,3 and 4 followed by dosing every 4 weeks	Adults:300 mg every 4 weeks Pediatrics: Weight < 50 kg: 75 mg every 4 weeks Weight ≥ 50 kg: 150 mg every 4 weeks
Stellara®	Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult: Weight ≤ 100 kg: 45 mg (some patients may require doses of 90 mg or maintenance dosing of every 8 weeks) Weight > 100 kg: 90 mg (some patients may require maintenance dosing of every 8 weeks) Pediatrics (Age 6 years and older): Weight < 60 kg: 0.75 mg/kg Weight ≥ 60 to ≤100 kg: 45 mg Weight > 100kg: 90 mg	90 mg every 8 weeks

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- May increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, consider discontinuing Ilumya® until the infection resolves.
- For female patients who are actively attempting to conceive:
  - MTX is a pregnancy category X and is absolutely contraindicated in pregnancy and is not recommended for female patients attempting to conceive.
  - Acitretin should not be used in females attempting to conceive because the drug is esterified in fat remaining in the system for up to three (3) years and has the potential to cause birth defects.
  - Cyclosporine is associated with low birth weights; thus, cyclosporine is not appropriate for female patients attempting to conceive.

References

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2. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of Ilumya® psoriasis with biologics. J Am Acad Dermatol. 2008; 58:826-850. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext. Accessed February 09, 2022.
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Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologic_DMARDs	01/05/2022	04/18/2022
Drug specific policy for Ilumya® was created based on RxA.592.Biologics_DMARDs: 1. Initial Approval Criteria, 1.A.4: Updated trial and failure criteria to rephrase and include phototherapy (psoralen plus ultraviolet A light [PUVA]). 2. Initial Approval Criteria, I.A.5 updated to remove Failure of two of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Skyrizi™, Stelara®, Taltz®. 3. Initial Approval Criteria, I.A.5. Updated to include Member meets both (a and b): a. Trial and failure of at least three (3) first line agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced. 4. Initial Approval Criteria, I.A.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 100 mg/dose subcutaneously. 5. Continued Therapy Approval Criteria II.A.3 was updated from If request is	02/09/2022	04/18/2022

for a dose increase, new dose does not exceed maximum dose indicated in background to If request is for a dose increase, new dose does not exceed 100 mg/dose subcutaneously 6. Appendix A: Updated to include abbreviations PUVA: Psoralen plus ultraviolet A light. 7. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 8. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 9. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 10. Appendix D, General Information: Updated to remove information regarding: Definition of failure of MTX or DMARDs 11. Appendix D, General Information: Updated to include information regarding warning and precaution. 12. References were reviewed and updated.		