Clinical Policy Title:	guselkumab
Policy Number:	RxA.729
Drug(s) Applied:	Tremfya®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Tremfya® is an interleukin-23 blocker indicated for the treatment of adult patients with:

- Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Active psoriatic arthritis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
guselkumab (Tremfya®)	PsO, PsA	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

Dosage Forms

- Single-dose prefilled syringe**:** 100 mg/mL
- Single-dose one-Press patient-controlled injector: 100 mg/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 Psorisis (PsO);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age 18 years of age or older;

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. Dose does not exceed 100 mg every 4 weeks for Initial dose and 100 mg every 8 weeks for maintenance dose.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Psoriatic Arthritis (must meet all)**:**
1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age 18 years of age or older;
4. Dose does not exceed 100 mg every 4 weeks for Initial dose and 100 mg every 8 weeks for maintenance dose.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (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 every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
PsO: Plaque Psoriasis
PsA: Psoriatic Arthritis
DMARDs: Disease-Modifying Antirheumatic Drugs
MTX: Methotrexate
FDA: Food and Drug Administration
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	**PsO:** 25 or 50 mg orally once daily	50 mg/day
methotrexate	**PsO:** 10 - 25 mg/week orally or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
cyclosporine (Sandimmune®, Neoral®)	**PsO:** 1 - 4 mg/kg/day orally divided twice daily	4 mg/kg/day
Cosentyx®	**PsO:** Adults:300 mg subcutaneous at weeks 0, 1, 2, 3, and 4, followed by 300 mg subcutaneous 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. **PsA:** With loading dose: 150 mg subcutaneous at week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks Without loading dose: 150 mg subcutaneously every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. Pediatric Patients 2 years and older: Recommended dosage is administered by subcutaneously injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.	PsO: Adults:300 mg every 4 weeks Pediatrics: Weight < 50 kg: 75 mg every 4 weeks Weight ≥ 50 kg: 150 mg every 4 weeks PsA: 300 mg every 4 weeks
Ilumya®	**PsO:** Initial dose: 100 mg subcutaneously at weeks 0 and 4 week Maintenance dose: 100 mg subcutaneously every 12 weeks Tildrakizumab should only be administered by a healthcare professional.	100 mg every 12 weeks
Xeljanz®	**PsA:** 5 mg orally twice daily use in combination with nonbiologic disease-modifying antirheumatic drugs.	10 mg/day
Xeljanz® XR	**PsA:** 11 mg orally once daily	11 mg/day
Rinvoq®	**PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Stelara®	**PsO:** Weight based dosing subcutaneously at weeks 0 and 4, followed by maintenance dose every 12 weeks	PsO: 90 mg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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 **PsA:** 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks	PsA; 45 mg every 12 weeks
Humira®	**PsO:** Initial dose: 80 mg Maintenance dose: 40 mg subcutaneously every other week starting one week after initial dose **PsA**: 40 mg subcutaneously every other week	40 mg every other week
Cimzia®	**PsA:** Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneously every other week (or 400 mg subcutaneously every 4 weeks) **PsO:** 400 mg subcutaneously every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg subcutaneous at 0, 2 and 4 weeks, followed by 200 mg subcutaneous every other week may be considered.	400 mg every 4 weeks
Enbrel®	**PsA:** 25 mg subcutaneously twice weekly or 50 mg subcutaneously once Weekly **PsO:** 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	
infliximab (Remicade®), Renflexis®, Avsola®, Inflectra®	**PsA, PsO:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks	5 mg/kg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Otezla®	**PsO, PsA:** 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 orall in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Orencia®	**PsA:** Intravenous: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneous: 125 mg once weekly	Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week
Siliq®	**PsO:** Initial dose: 210 mg subcutaneously at weeks 0, 1, and 2 Maintenance dose: 210 mg subcutaneously every 2 weeks	210 mg every 2 weeks
Simponi Aria®	**PsA :** Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks	2 mg/kg every 8 weeks
Skyrizi®	**PsO:** 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Taltz®	**PsO:** 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 subcutaneously 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 **PsA:** Initial dose: 160 mg (two 80 mg injections) subcutaneously Maintenance dose: 80 mg subcutaneously every 4 weeks	80 mg every 4 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 reactions to guselkumab 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

- Psoriatic Arthritis: According to the 2018 American College of Rheumatology and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.
- 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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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 Trefmya® 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. Appendix A: Updated to include abbreviations PUVA: Psoralen plus ultraviolet A light. 3. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 4. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 5. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 6. References were reviewed and updated.	02/15/2022	04/18/2022