Clinical Policy Title:	ustekinumab
Policy Number:	RxA.747
Drug(s) Applied:	Stelara®
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Stelara® is a human interleukin-12 and -23 antagonist indicated for the treatment of:

Adult patients with:

- Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis (PsA), alone or in combination with methotrexate
- Moderately to severely active Crohn's disease (CD)
- Moderately to severely active ulcerative colitis (UC)

Pediatric patients 6 years and older with:

- Moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ustekinumab (Stelara®)	PsO	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
	PsA	45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12	45 mg every 12 weeks

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
		weeks For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks	
	CD UC	Weight based dosing intravenous at initial dose, followed by 90 mg subcutaneously every 8 weeks Weight ≤ 55 kg: 260 mg Weight 55 kg to 85 kg: 390 mg Weight > 85 kg: 520 mg	90 mg every 8 weeks

Dosage Forms

Subcutaneous Injection:

- Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe
- Injection: 45 mg/0.5 mL solution in a single-dose vial

Intravenous Infusion:

- Injection: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial

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. Crohn's Disease (must meet all)**:**

1. Diagnosis of Crohn's Disease (CD);
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced;

*Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required

5. Dose does not exceed 90 mg every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. 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 ≥ 6 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. Dose does not exceed 90 mg every 8 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Psoriatic Arthritis (must meet all):
1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Dose does not exceed 45 mg every 12 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Ulcerative Colitis (must meet all)**:**
1. Diagnosis of UC;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects experienced;
      *Exception: If one biologic DMARD that is FDA-approved for ulcerative colitis has been previously tried, then trial of a conventional systemic agent is not required;
5. Dose does not exceed 90 mg every 8 weeks.

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 one of the following: (a or b);
   a. For UC, CD, PsO: 90 mg every 8 weeks;
   b. For PsA: 45 mg every 12 weeks.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

PsO: plaque psoriasis
PsA: psoriatic arthritis
CD: Crohn's disease
DMARDs: disease-modifying antirheumatic drugs
UC: ulcerative colitis
MTX: methotrexate
TNF: tumor necrosis factor
FDA: Food and Drug Administration
MP: mercaptopurine
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
azathioprine (Azasan®, Imuran®)	**CD (off-label), UC (off-label):** 1.5 – 2 mg/kg/day orally	2.5 mg/kg/day
Corticosteroids	**CD (off-label:** prednisone 40 mg orally once daily for 2 weeks or intravenously 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg orally once daily	Various
cyclosporine (Sandimmune®, Neoral®)	**PsO:** 1 – 4 mg/kg/day orally divided twice daily	PsO: 4 mg/kg/day
mercaptopurine (Purixan®)	**CD (off-label), UC (off-label):** 50 mg orally once daily or 1 – 2 mg/kg/day orally	2 mg/kg/day
methotrexate	**CD (off-label):** 15 – 25 mg/week intramuscularly or subcutaneously **PsO:** 10 – 25 mg/week orally or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
mesalamine (Pentasa®)	**CD, UC:** 1,000 mg orally four times daily	4 g/day
sulfasalazine (Azulfidine®)	**UC:** Initial dose: Adults: 3 – 4 g/day orally in divided doses (not to exceed Q8 hrs) Pediatrics: 40 – 60 mg/kg/day orally in 3 –6 divided doses Maintenance dose: Adults: 2 g orally once daily Pediatrics: 30 mg/kg/day orally in 4 divided doses	UC: 4 g/day
tacrolimus (Prograf®)	**CD (off-label):** 0.27 mg/kg/day orally in divided doses or 0.15 – 0.29 mg/kg/day orally	N/A
Biologic DMARDs		
Humira®	**UC:** Initial dose: Adults:160 mg subcutaneously on Day 1 (given in one day or split over two consecutive days), then 80 mg subcutaneously on Day 15 Pediatrics: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg subcutaneous on Day 8, then 40 mg subcutaneously on day 15 Weight ≥ 40 kg (88 lbs): 160 mg subcutaneously Day 1, then 80 mg on day 8 and day 15 Maintenance dose: Adults:40 mg subcutaneously every other week starting on Day 29 Pediatrics: Weight 20 kg (44 lbs) to < 40 kg (88 lbs): 40 mg every other week or 20 mg every week starting on day 29 Weight ≥ 40 kg(88 lbs): 80 mg every other week or 40 mg every week starting on day 29 **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 **CD: Initial dose:** Adults: 160 mg subcutaneously on Day 1, then 80 mg subcutaneously on Day 15 Pediatrics: Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 80 mg subcutaneously on Day 1, then 40 mg subcutaneously on Day 15 Weight ≥ 40 kg (88 lbs)160 mg subcutaneously on Day 1, then 80 mg subcutaneously on Day 15 **Maintenance dose:**	40 mg every other week UC: Adults:40 mg every other week Pediatrics: 80 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Adults: 40 mg subcutaneously every other week starting on Day 29 Pediatrics: Weight 17 kg (37 lbs) to < 40 kg (88 lbs): 20 mg subcutaneously every other week starting on Day 29 Weight ≥ 40 kg (88 lbs): 40 mg subcutaneously every other week starting on Day 29	
Cosentyx®	**PsA:** With loading dose: 150 mg subcutaneously 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: Recommended dosage is 300 mg by subcutaneously injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable. Children and Adolescents 6 to 17 years weighing 50 kg or more: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 150 mg subcutaneously every 4 weeks. Children and Adolescents 6 to 17 years weighing less than 50 kg: 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 75 mg subcutaneously every 4 weeks	PsA: 300 mg every 4 weeks PsO Adults: 300 mg/dose subcutaneously Adolescents weighing 50 kg or more: 150 mg/dose subcutaneously. weighing less than 50 kg: 75 mg/dose subcutaneously.
infliximab (Remicade®), Renflexis®, Inflectra®, Avsola®	**Adult and Pediatrics** ≥ 6 years old: **UC, CD: Initial dose:** 5 mg/kg intravenously at weeks 0, 2 and 6 **Maintenance dose:** 5 mg/kg intravenously every 8 weeks. For CD: Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response. **PsA, PsO:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks	PsA, PsO: 5 mg/kg every 8 weeks CD: Adults: 10 mg/kg every 8 weeks UC, Adults: 5 mg/kg every 8 weeks Pediatrics: 5 mg/kg every 8 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Simponi Aria®	**PsA:** Initial dose: 2 mg/kg intravenously at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenously every 8 weeks	PsA: 2 mg/kg every 8 weeks
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 orally in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	60 mg/day
Xeljanz® / Xeljanz® oral Solution, Xeljanz® XR	Xeljanz®: **PsA:** 5 mg orally twice daily **PsA:** use in combination with nonbiologic disease-modifying antirheumatic drugs **UC:** Induction:10 mg orally twice daily for at least 8 weeks, based on therapeutic response, may continue 10 mg twice daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue after 16 weeks of 10 mg twice daily if adequate therapeutic benefit is not achieved. Maintenance: 5 mg twice daily; if loss of response on 5 mg twice daily, then use 10 mg twice daily after assessing the benefits and risks and use for the shortest duration; use lowest effective dose to maintain response Xeljanz® XR: **PsA**: 11 mg orally once daily **UC:** Induction: 22 mg once daily for at least 8 weeks; may continue 22 mg once daily for a maximum of 16 weeks or transition to maintenance dose. Discontinue therapy if inadequate response achieved after 16 weeks using 22 mg once daily. Maintenance: 11 mg once daily; if loss of response on 11 mg once daily; then use 22 mg once daily for the shortest duration; use lowest effective dose to maintain response.	Xeljanz®: PsA : 10 mg/day UC: 20 mg/day Xeljanz® / Xeljanz® oral Solution: 5 mg or 5 ml twice daily Xeljanz® XR: PsA: 11 mg/day UC: 22 mg/day
Enbrel®	**PsA**: Adult: 50 mg once weekly with or without methotrexate (MTX) **PsO:** Adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly Pediatric PsO: Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly	PsA**:** Adults 50 mg/week subcutaneously. Induction therapy for psoriatic arthritis should not exceed 100 mg/week with no more than 50 mg/dose subcutaneously.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Weight ≥ 63 kg: 50 mg subcutaneously once weekly	PsO: 50 mg/week
Ilumya®	**PsO:** 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
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 PsA: Patients switching from intravenous use to subcutaneous use, administer first subcutaneous dose instead of next scheduled intravenous dose. For PsA: Intravenous loading dose is not recommended	PsA: Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week
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
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®	**PsA:** 50 mg subcutaneously once monthly **UC:** Initial dose: 200 mg subcutaneously at week 0, then 100 mg subcutaneously at week 2 Maintenance dose: 100 mg subcutaneously every 4 weeks	PsA: 50 mg/month UC: 100 mg every 4 weeks
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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.	PsO: 80 mg every 4 weeks PsA: 80 mg every 4 weeks
Skyrizi®	**PsA, PsO:** 150 mg subcutaneously at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Entyvio®	**UC, CD:** Initial dose: 300 mg intravenously at weeks 0, 2, and 6 Maintenance dose: 300 mg intravenously every 8 weeks	300 mg per dose
Tysabri®	**CD:** 300 mg intravenously every 4 weeks	300 mg every 4 Weeks
Cimzia®	**CD:** Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks Maintenance dose: 400 mg 400 mg subcutaneously at 0, 2, and 4 weeks every 4 weeks **PsA:** Initial dose: 400 mg 400 mg subcutaneously at 0, 2, and 4 weeks at 0, 2, and 4 weeks. Maintenance dose: 200 mg 400 mg subcutaneously at 0, 2, and 4 weeks every other week (or 400 mg subcutaneous every 4 weeks) **PsO:** 400 mg 400 mg subcutaneously at 0, 2, and 4 weeks	PsA, CD:400 mg every 4 weeks PsO: 400 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg 400 mg subcutaneously at 0, 2, and 4 weeks at 0, 2 and 4 weeks, followed by 200 mg subcutaneously every other week may be considered.	

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):
  - Clinically significant hypersensitivity to ustekinumab 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

- PsA: According to the 2019 American College of Rheumatology TNF inhibitors is recommended over other biologics for use in treatment-naïve patients with psoriatic arthritis, and in those who were previously treated with an oral therapy.

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 Stelara was created based on RxA.592.Biologic_DMARDs 1. Dosing Information, Dosing Regimen: Updated dosing information from 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks to 45 mg subcutaneously at weeks 0 and 4, followed by 45 mg every 12 weeks For patients with co-existent moderate-to-severe plaque psoriasis weighing greater than 100 kg, the recommended dosage is 90 mg administered subcutaneously initially and 4 weeks later, followed by 90 mg administered subcutaneously every 12 weeks indication PsA. 2. Initial Approval Criteria, I.A.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 3. Initial Approval Criteria, 1.B.4: Updated trial and failure criteria to rephrase and include	02/16/2022	04/18/2022

phototherapy (psoralen plus ultraviolet A light [PUVA]). 4. Appendix A: Updated to include abbreviations PUVA. 5. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 6. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 7. Appendix D, General Information: Updated to remove information regarding: (a, b, c, d and e) a. Ulcerative Colitis; b. Medical justification supporting inability to use an immunomodulator for Crohn's disease; c. Definition of failure of MTX or DMARDs; d. Examples of positive response to therapy 8. References were reviewed and updated.		