VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Inflammatory Conditions Care Value Policy

DATE REVIEWED: 12/11/2019; selected revision 12/18/2019 and 01/15/2020

DRUGS AFFECTED:

- Actemra® (tocilizumab subcutaneous [SC] injection – Genentech/Roche)
- Cimzia® (certolizumab pegol SC injection [lyophilized] and SC injection [solution] – UCB)
- Cosentyx® (secukinumab SC injection)
- Enbrel® (etanercept SC injection – Immunex)
- Humira® (adalimumab SC injection – AbbVie, Inc.)
- Ilumya™ (tildrakizumab-asmn for subcutaneous injection – Sun/Merck)
- Kevzara™ (sarilumab for subcutaneous injection – Regeneron)
- Kineret® (anakinra SC injection – Swedish Orphan Biovitrim)
- Olumiant® (baricitinib tablets – Lilly)
- Orencia® (abatacept SC injection – Bristol Myers Squibb)
- Otezla® (apremilast tablets – Celgene Corporation)
- Rinvoq™ (upadacitinib extended-release tablets – AbbVie)
- Siliq™ (brodalumab SC injection – Valeant Pharmaceuticals)
- Simponi® (golimumab SC injection – Janssen Biotech/Johnson & Johnson)
- Skyrizi™ (risankizumab-rzaa subcutaneous injection – Abbvie)
- Stelara® (ustekinumab SC injection – Janssen Biotech/Johnson & Johnson)
- Taltz® (ixekizumab SC injection – Eli Lilly and Company)
- Tremfya™ (guselkumab for subcutaneous injection– Janssen Biotech/Johnson & Johnson)
- Xeljanz® (tofacitinib tablets – Pfizer)
- Xeljanz® XR (tofacitinib extended-release tablets – Pfizer)

OVERVIEW

Several products are available for use in inflammatory conditions such as rheumatoid arthritis (RA), ankylosing spondylitis (AS), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), plaque psoriasis, Crohn's disease, and ulcerative colitis (UC).[1-20] This policy involves the use of the products listed above.

The FDA-approved indications for each product listed in this policy are documented in Appendix A. For more information on criteria within a Prior Authorization (PA) program by specific condition refer to the respective *ESI Standard Inflammatory Conditions Prior Authorization Policy.*

Preferred and Non-Preferred Products.

	Rheumatoid Conditions				Dermatology	Gastrointestinal Conditions	
	RA	**AS**	**JIA**	**PsA**	**Psoriasis**	**CD**	**UC**
Step 1 **Preferred**	• Actemra SC • Enbrel • Humira • Rinvoq • Xeljanz/XR	• Cosentyx • Enbrel • Humira	• Enbrel • Humira	• Cosentyx • Enbrel • Humira • Stelara SC • Xeljanz/XR	• Cosentyx • Humira • Otezla • Skyrizi • Stelara SC • Tremfya	• Humira • Stelara SC	• Humira
Step 2 **Non-Preferred** (directed to **ONE** Step 1 agent)	--	--	• Actemra SC *Directed to Humira specifically. JIA Step for Actemra SC is only for PJIA.*	• Otezla	• Enbrel – *Step only for pts ≥ 18 years of age. Directed to Humira specifically.*	• Cimzia – *Directed to Humira specifically.*	• Simponi SC • Stelara SC • Xeljanz/XR
Step 3a **Non-Preferred** (directed to **TWO** Step 1 agents) [documentation required]*	• Cimzia • Orencia SC • Simponi SC • Kevzara • Kineret • Olumiant	• Cimzia • Simponi SC • Taltz	--	• Cimzia • Orencia SC • Simponi SC • Taltz	• Ilumya • Siliq • Cimzia	--	--
Step 3b **Non-Preferred** (directed to **TWO** Step 1 or Step 2 agents) [documentation required]*	--	--	• Orencia SC	--	--	--	--
Step 3c **Non-Preferred** (directed to **THREE** Step 1 agents) [documentation required]*	--	--	--	--	• Taltz	--	--

SC – Subcutaneous; RA – Rheumatoid arthritis; AS – Ankylosing spondylitis; JIA – Juvenile idiopathic arthritis; PsA – Psoriatic arthritis; CD – Crohn's disease; UC – Ulcerative colitis; PJIA – Polyarticular juvenile idiopathic arthritis; Pts – Patients.

* The prescriber must provide written documentation supporting the trial of Preferred agents, noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

POLICY STATEMENT

For all Non-Preferred Products, this program requires the patient to meet *ESI Standard Inflammatory Conditions Prior Authorization* criteria. Additionally, this program requires trial(s) of the Preferred product(s) according to the tables above, when clinically appropriate, prior to the approval of the Non-Preferred products. There are also situations when trials of Non-Preferred agents will be considered; see criteria below. Prior Authorization in not required for agents which are Preferred for all indications. Other details of the program are as follows:

- **Continuation of Therapy:** Approval for a patient continuing therapy with a **Non-Preferred** SC or oral agent must be supported with verification, noted in the criteria as either [verification in prescription claims history required] or, if not available, as [verification by prescribing physician required].
  - If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received the Non-Preferred product for the specified period of time (90 or 120 days) within a 130-day look-back period; OR
  - When 130 days of the patient's prescription claim history file is unavailable for verification, the prescriber must verify that the patient has been receiving the Non-Preferred product for a specified

period of time (90 or 120 days), AND that the patient has been receiving the Non-Preferred product via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to the Non-Preferred product).
  - For patients continuing therapy, other conditions may also apply. Refer to criteria below.
- **Approval Duration:** All approvals for continuation of therapy for Non-Preferred products are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Automation: None

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Actemra SC	**1. Juvenile Idiopathic Arthritis (JIA)/Juvenile Rheumatoid Arthritis (JRA) – Initial Therapy.** **A)** Approve Actemra SC for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Actemra SC PA Policy* criteria; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has tried Humira. Note: A trial of Enbrel or an infliximab product (e.g., Remicade, Inflectra, Renflexis) also counts; OR **b)** According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Actemra SC PA Policy* criteria), but criterion 1Aii is not met: offer to review for the Preferred product (Humira) using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria. **2. JIA – Patients Currently Taking Actemra (SC or IV).** **A)** Approve Actemra SC for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Actemra SC Policy* criteria for Patients Currently taking Actemra SC or IV; AND **ii.** The patient meets ONE of the following conditions (a, b, c, or d): **a)** The patient has been established on Actemra SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Actemra SC was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Actemra SC for at least 90 days AND the patient has been receiving Actemra SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Actemra SC); OR **b)** According to the prescribing physician, the patient has been established on Actemra IV for at least 90 days; OR

	c) The patient has JIA and has tried Humira. Note: A trial of Enbrel or an infliximab product (e.g., Inflectra, Remicade, Renflexis) also counts; OR **d)** According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Actemra SC PA Policy* criteria), but criterion 2Aii is not met, offer to review for the Preferred product (Humira) using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria. **3. All Other Conditions** (including systemic juvenile idiopathic arthritis [SJIA]). Approve Actemra SC (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Actemra SC PA Policy* criteria.
Cimzia	**1. Rheumatoid Arthritis (RA) – Initial Therapy.** **A)** Approve Cimzia for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria; AND **ii.** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **2. Ankylosing Spondylitis (AS) – Initial Therapy**. **A)** Approve Cimzia for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, or Humira) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **3. Psoriatic Arthritis (PsA) – Initial Therapy**. **A)** Approve Cimzia for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. **B)** If the patient has met criterion 3Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 3Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, Humira, Stelara, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria). **4. Plaque Psoriasis – Initial Therapy.** **A)** Approve Cimzia for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya [documentation required]. **B)** If the patient has met criterion 4Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 4Aii is not met, offer to review for a Preferred product (Cosentyx,

	Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the respective ESI Standard Inflammatory Conditions PA Policy criteria). **5. Crohn's Disease (CD) in an Adult – Initial Therapy.** **A)** Approve Cimzia for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria; AND **ii.** The patient has tried Humira; OR **B)** If the patient has met criterion 5Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 5Aii is not met, offer to review for the Preferred product (Humira or Stelara SC) using the *ESI Standard Inflammatory Conditions –PA Policy* criteria. **6. RA, AS, PsA, Plaque Psoriasis, or CD – Patients Currently Taking Cimzia.** **A)** Approve Cimzia for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria for Patients Currently taking Cimzia; AND **ii.** The patient meets ONE of the following conditions (a, b, c, d, e, or f): **a)** The patient has been established on Cimzia for at least 90 days and prescription claims history indicates at least a 90-day supply of Cimzia was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Cimzia for at least 90 days AND the patient has been receiving Cimzia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Cimzia); OR **b)** The patient has RA and has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR **c)** The patient has AS and has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]; OR **d)** The patient has PsA and has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR **e)** The patient has plaque psoriasis and has tried TWO of Coxentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya [documentation required]; OR **f)** The patient has CD and has tried Humira. **B)** If the patient has met criterion 6Ai (the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria), but criterion 6Aii is not met, offer to review for a Preferred product using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria: **i.** Patients with RA: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR **ii.** Patients with AS: Cosentyx, Enbrel, or Humira **iii.** Patients with PsA: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR **iv.** Patients with plaque psoriasis: Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya **v.** Patients with CD: Humira or Stelara SC **7. Other Conditions.** Approve Cimzia (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Cimzia PA Policy* criteria.
Enbrel	**1. Plaque Psoriasis in an Adult ≥ 18 years of age – Initial Therapy.** (For patients < 18 years of age, see criterion #3.) **A)** Approve Enbrel for 3 months if the patient meets the following conditions (i and ii):

	i. The patient meets the *ESI Standard Inflammatory Conditions – Enbrel PA Policy* criteria; AND **ii.** The patient has tried Humira. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Enbrel PA Policy* criteria), but criterion 1Aii is not met, offer to review for Humira using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy criteria*. **2. Plaque Psoriasis in an Adult ≥ 18 years of age – Patients Currently Taking Enbrel.** (For patients < 18 years of age, see criterion #3.) **A)** Approve Enbrel for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Enbrel PA Policy* criteria for Patients Currently taking Enbrel; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Enbrel for at least 90 days and prescription claims history indicates at least a 90-day supply of Enbrel was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Enbrel for at least 90 days AND the patient has been receiving Enbrel via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Enbrel); OR **b)** The patient has tried Humira. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Enbrel PA Policy* criteria), but criterion 2Aii is not met, offer to review for Humira using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy criteria.* **3. Other Conditions (including Plaque Psoriasis in a Patient < 18 years of age).** Approve Enbrel (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Enbrel PA Policy* criteria.
Ilumya	**1. Plaque Psoriasis – Initial Therapy.** **A)** Approve Ilumya for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Ilumya PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya [documentation required]. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Ilumya PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **2. Plaque Psoriasis – Patients Currently Taking Ilumya.** **A)** Approve Ilumya for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Ilumya PA Policy* criteria for Patients Currently taking Ilumya; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Ilumya for at least 90 days and prescription claims history indicates at least a 90-day supply of Ilumya was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Ilumya for at least 90 days AND the

	patient has been receiving Ilumya via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Ilumya); OR **b)** The patient has plaque psoriasis and has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Ilumya PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. Other Conditions.** Approve Ilumya (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Ilumya PA Policy* criteria.
Kevzara	**1. Rheumatoid Arthritis (RA) – Initial Therapy.** **A)** Approve Kevzara for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Kevzara PA Policy* criteria; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]; OR **b)** According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Kevzara PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **2. RA – Patients Currently Taking Kevzara.** **A)** Approve Kevzara for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Kevzara PA Policy* criteria for Patients Currently taking Kevzara; AND **ii.** The patient meets ONE of the following conditions (a, b, or c): **a)** The patient has been established on Kevzara for at least 90 days and prescription claims history indicates at least a 90-day supply of Kevzara was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kevzara for at least 90 days AND the patient has been receiving Kevzara via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kevzara); OR **b)** A trial of TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]; OR **c)** According to the prescribing physician, the patient has heart failure OR a previously treated lymphoproliferative disorder.

	B) If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Kevzara PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. Other Conditions.** Approve Kevzara (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Kevzara PA Policy* criteria.
Kineret	**1. Rheumatoid Arthritis (RA) – Initial Therapy.** **A)** Approve Kineret for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Kineret PA Policy* criteria; AND **ii.** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, Orencia IV or SC, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, and Simponi Aria or SC also counts [documentation required]. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Kineret PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **2. RA – Patients Currently Taking Kineret.** **A)** Approve Kineret for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Kineret PA Policy* criteria for Patients Currently taking Kineret; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Kineret at least 90 days and prescription claims history indicates at least a 90-day supply of Kineret was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kineret for at least 90 days AND the patient has been receiving Kineret via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kineret); OR **b)** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, Orencia IV or SC, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, or Simponi Aria or SC also counts [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Kineret PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. Other Conditions (e.g., Cryopyrin-Associated Periodic Syndromes [CAPS], SJIA).** Approve Kineret (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Kineret PA Policy* criteria.
Olumiant	**1. Rheumatoid Arthritis (RA) – Initial Therapy.** **A)** Approve Olumiant for 3 months if the patient meets the following conditions (i and ii):

	i. The patient meets the *ESI Standard Inflammatory Conditions – Olumiant PA Policy* criteria; AND **ii.** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Olumiant PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **2. RA – Patients Currently Taking Olumiant.** **A)** Approve Olumiant for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Olumiant PA Policy* criteria for Patients Currently taking Olumiant; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Olumiant for at least 90 days and prescription claims history indicates at least a 90-day supply of Olumiant was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Olumiant for at least 90 days AND the patient has been receiving Olumiant via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Olumiant); OR **b)** A trial of TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Orencia IV or SC, or Simponi Aria or SC also counts [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Olumiant PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. Other Conditions.** Approve Olumiant (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Olumiant PA Policy* criteria.
Orencia SC	**1. Rheumatoid Arthritis (RA), Initial Therapy.** **A)** Approve Orencia SC for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, or Simponi Aria or SC also counts [documentation required]; OR **b)** According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

B) If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria.

2. Juvenile Idiopathic Arthritis (JIA)/Juvenile Rheumatoid Arthritis (JRA) – Initial Therapy.

A) Approve Orencia SC for 3 months if the patient meets the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria; AND

ii. The patient meets ONE of the following conditions (a or b):

a) The patient has tried TWO of Enbrel, Humira, and Actemra SC. Note: A trial of Actemra IV, Orencia IV, or an infliximab product (e.g., Remicade, Inflectra, Renflexis) also counts[documentation required]; OR

b) According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

B) If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria), but criterion 2Aii is not met: offer to review for a Step 1 or 2 product (Enbrel, Humira, or Actemra SC) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria.

3. Psoriatic Arthritis (PsA) – Initial Therapy.

A) Approve Orencia SC for 3 months if the patient meets the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria; AND

ii. The patient meets ONE of the following conditions (a or b):

a) The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g., Remicade, Inflectra, Renflexis), or Simponi Aria or SC also counts [documentation required]; OR

b) According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection.

B) If the patient has met criterion 3Ai (the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria), but criterion 3Aii is not met: offer to review for a Preferred product (Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria.

4. RA, JIA, or PsA – Patients Currently Taking Orencia (SC or IV).

A) Approve Orencia SC for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Orencia SC Policy* criteria for Patients Currently taking Orencia SC or IV; AND

ii. The patient meets ONE of the following conditions (a, b, c, d, e, or f):

a) The patient has been established on Orencia SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Orencia SC was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Orencia SC for at least 90 days AND the patient has been receiving Orencia SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Orencia SC); OR

	b) According to the prescribing physician, the patient has been established on Orencia IV for at least 90 days; OR **c)** The patient has RA and has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Simponi (Aria or SC) also counts [documentation required]; OR **d)** The patient has JIA and has tried TWO of Enbrel, Humira, and Actemra SC. Note: A trial of Actemra IV, Orencia IV, or an infliximab product (e.g., Inflectra, Remicade, Renflexis) also counts [documentation required]; OR **e)** The patient has PsA and has tried TWO of Cosentyx, Enbrel, Humira, or Stelara SC [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g., Remicade, Inflectra, Renflexis), or Simponi Aria or SC also counts [documentation required]; OR **f)** According to the prescribing physician, the patient has heart failure, a previously treated lymphoproliferative disorder, OR a previous serious infection. **B)** If the patient has met criterion 4Ai (the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria), but criterion 4Aii is not met, offer to review for a the following products using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **i.** RA: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR **ii.** JIA: Enbrel, Humira, and Actemra SC **iii.** PsA: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR **5. Other Conditions.** Approve Orencia SC (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Orencia SC PA Policy* criteria.
Otezla	**1. Psoriatic Arthritis (PsA) – Initial Therapy.** **A)** Approve Otezla for 4 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Otezla PA Policy* criteria, Initial Therapy; AND **ii.** The patient meets ONE of the following (a or b): **a)** The patient has tried ONE of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljan/XR. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR **b)** The patient has experienced a previous intolerance or has one of the following conditions or relative contraindications to use of a TNFi: a history of hepatitis B, hepatitis C, demyelinating disease, or malignancy; heart failure; the patient is on chronic systemic corticosteroid therapy (e.g., prednisone, dexamethasone); the patient has a chronic infection or is at high risk of infection (e.g., human immunodeficiency virus [HIV], malignancy, neutropenia, diabetes), as determined by the prescribing physician; or the patient has a history of recurrent infections, as determined by the prescribing physician. **B)** If the patient meets criterion 1Ai (the *ESI Standard Inflammatory Conditions – Otezla PA Policy* criteria for Otezla), but criterion 1Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, Humira, or Stelara SC) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **2. PsA – Patients Currently Receiving Otezla.** **A)** Approve for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Otezla PA Policy* criteria; AND

	ii. The patient meets ONE of the following conditions (a, b, or c): **a)** The patient has been established on Otezla for at least 120 days and prescription claims history indicates at least a 120-day supply of Otezla was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Otezla for at least 120 days AND the patient has been receiving Otezla via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Otezla); OR **b)** The patient has tried ONE of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR **c)** The patient has experienced a previous intolerance or has one of the following conditions or relative contraindications to use of a TNFi: a history of hepatitis B, hepatitis C, demyelinating disease, or malignancy; heart failure; the patient is on chronic systemic corticosteroid therapy (e.g., prednisone, dexamethasone); the patient has a chronic infection or is at high risk of infection (e.g., HIV, malignancy, neutropenia, diabetes), as determined by the prescribing physician; or the patient has a history of recurrent infections, as determined by the prescribing physician. **B)** If the patient meets criterion 2Ai (the *ESI Standard Inflammatory Conditions – Otezla PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions PA Policy* criteria. **3. Other Conditions (e.g., plaque psoriasis).** Approve Otezla (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Otezla PA Policy* criteria.
Siliq	**1. Plaque Psoriasis – Initial Therapy.** **A)** Approve Siliq for 3 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Siliq PA Policy* criteria for plaque psoriasis; AND **ii.** The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya [documentation required]. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Siliq PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **2. Plaque Psoriasis – Patients Currently Taking Siliq.** **A)** Approve Siliq for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Siliq PA Policy* criteria for Patients Currently taking Siliq; AND **ii.** The patient meets ONE of the following conditions (a or b): **(1)** The patient has been established on Siliq for at least 90 days and prescription claims history indicates at least a 90-day supply of Siliq was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Siliq for at least 90 days AND the

	patient has been receiving Siliq via paid claims (e.g., patient has <u>not</u> been receiving samples or coupons or other types of waivers in order to obtain access to Siliq); AND meets at least ONE of the following [(1), (2), (3), <u>or</u> (4)]: **(1)** According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Taltz; OR **(2)** The patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic; OR **(3)** The patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated. <u>Note</u>: Examples of systemic agents taken for psoriasis include methotrexate, acitretin, and cyclosporine; OR **(4)** The patient is taking the requested agent in combination with phototherapy. <u>Note</u>: Examples include narrowband ultraviolet B [NB-UVB] phototherapy; <u>Note</u>: For patients who have not tried the Preferred Products, <u>Cosentyx</u> is approved for patients who meet criterion 2Aiia but do not meet 2Aiia[(1), (2), (3), or (4)]; OR **(2)** The patient has tried TWO of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Siliq PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (<u>Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya</u>) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. <u>Other Conditions</u>.** Approve <u>Siliq</u> (initial therapy for a duration as directed or <u>1 year</u> for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Siliq PA Policy* criteria.
Simponi SC	**1. <u>Rheumatoid Arthritis (RA) – Initial Therapy</u>.** **A)** Approve <u>Simponi SC</u> for 3 months if the patient meets the following conditions (i <u>and</u> ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria; AND **ii.** The patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. <u>Note</u>: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (<u>Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR</u>) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **2. <u>Ankylosing Spondylitis (AS) – Initial Therapy</u>.** **A)** Approve <u>Simponi SC</u> for 3 months if the patient meets the following conditions (i <u>and</u> ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (<u>Cosentyx, Enbrel, or Humira</u>) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria. **3. <u>Psoriatic Arthritis (PsA) – Initial Therapy</u>.** **A)** Approve <u>Simponi SC</u> for 3 months if the patient meets the following conditions (i <u>and</u> ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria; AND

ii. The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product.

B) If the patient has met criterion 3Ai (the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria), but criterion 3Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria.

4. Ulcerative Colitis (UC) – Initial Therapy.

A) Approve Simponi SC for 3 months if the patient meets the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria; AND

ii. The patient has tried Humira.

B) If the patient has met criterion 4Ai (the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria), but criterion 4Aii is not met, offer to review for a Preferred Product (Humira) using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria.

5. RA, AS, PsA, or UC – Patients Currently Taking Simponi SC or Aria.

A) Approve Simponi SC for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria for Patients Currently taking Simponi (SC or Aria); AND

ii. The patient meets ONE of the following conditions (a, b, c, d, e, or f):

(1) The patient has been established on Simponi SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi SC was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Simponi SC for at least 90 days AND the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC); OR

(2) According to the prescribing physician, the patient has been established on Simponi Aria for at least 90 days; OR

(3) The patient has RA and has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR

(4) The patient has AS and has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]; OR

(5) The patient has PsA and has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product; OR

(6) The patient has UC and has tried Humira.

B) If the patient has met criterion 5Ai (the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria), but criterion 5Aii is not met, offer to review for a Preferred product using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria:

i. Patients with RA: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR

ii. Patients with AS: Cosentyx, Enbrel, or Humira

iii. Patients with PsA: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR

iv. Patients with UC: Humira

	6. <u>Other Conditions</u>. Approve <u>Simponi SC</u> (initial therapy for a duration as directed or <u>1 year</u> for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Simponi SC PA Policy* criteria.
Stelara SC	**1. Ulcerative Colitis – Initial Therapy.** **A)** Approve Stelara SC for 3 months if the patient meets the following conditions (i <u>and</u> ii): **i.** The patient meets the ESI Standard Inflammatory Conditions – Stelara SC PA Policy criteria; AND **ii.** The patient meets ONE of the following (a <u>or</u> b): **a)** The patient has tried Humira. <u>Note</u>: A trial of an infliximab product (e.g., Remicade, Inflectra, Renflexis) or Simponi SC also counts; OR **b)** The patient has already received a single induction dose with Stelara IV. **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Stelara SC PA Policy* criteria), but criterion 1Aii is not met, offer to review for the Preferred product (<u>Humira</u>) using the *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria. **2.<u>Ulcerative Colitis – Patients Currently Taking Stelara IV or SC</u>.** **A)** Approve <u>Stelara SC</u> for 1 year if the patient meets BOTH of the following conditions (i <u>and</u> ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Stelara SC PA Policy* criteria for Patients Currently taking Stelara); AND **ii.** The patient meets ONE of the following conditions (a, b, <u>or</u> c): **a)** The patient has been established on Stelara SC for at least 90 days <u>and</u> prescription claims history indicates <u>at least a 90-day supply of Stelara SC was dispensed within the past 130 days</u> [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. <u>Note</u>: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Stelara SC for at least 90 days AND the patient has been receiving Stalara SC via paid claims (e.g., patient has <u>not</u> been receiving samples or coupons or other types of waivers in order to obtain access to Stalara SC); OR **b)** The patient has tried Humira. <u>Note</u>: A trial of an infliximab product (e.g., Remicade, Inflectra, Renflexis) or Simponi SC also counts.; OR **c)** The patient has already received a single induction dose with Stelara IV. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Stelara SC PA Policy* criteria but criterion 2Aii is not met, offer to review for a Preferred product (Humira) using the respective *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria. **<u>3. Other Conditions</u>.** Approve Stelara SC (initial therapy for a duration as directed or <u>1 year</u> for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Stelara SC PA Policy* criteria.
Taltz	**1. <u>Ankylosing Spondylitis – Initial Therapy.</u>** **A)** Approve Taltz for 3 months if the patient meets the following conditions (i <u>and</u> ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria; AND **ii.** The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]. <u>Note</u>: A trial of Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), or Simponi (Aria or SC) also counts [documentation required]; AND **B)** If the patient has met criterion 1Ai (the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria), but criterion 1Aii is not met, offer to review for a Preferred product (<u>Cosentyx,</u>

Humira, Enbrel) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria.

2. Plaque Psoriasis – Initial Therapy.

A) Approve Taltz for 3 months if the patient meets the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria; AND

ii. The patient has tried THREE of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, and Tremfya [documentation required].

B) If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria), but criterion 2Aii is not met, offer to review for a Preferred product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria.

3. Psoriatic Arthritis (PsA) – Initial Therapy.

A) Approve Taltz for 3 months if the patient meets the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria; AND

ii. The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product.

B) If the patient has met criterion 3Ai (the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria), but criterion 3Aii is not met, offer to review for a Preferred product (Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR) using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria

4. AS, Plaque Psoriasis, or PsA – Patients Currently Taking Taltz.

A) Approve Taltz for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The patient meets the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria for Patients Currently taking Taltz; AND

ii. The patient meets ONE of the following conditions (a, b, c, or d):

a) The patient has been established on Taltz for at least 90 days and prescription claims history indicates at least a 90-day supply of Taltz was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Taltz for at least 90 days AND the patient has been receiving Taltz via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Taltz); AND meets at least ONE of the following [(1), (2), (3), or (4)]:

(1) According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Siliq; OR

(2) The patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic; OR

(3) The patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated.

Note: Examples of systemic agents taken for psoriasis include methotrexate, acitretin, and cyclosporine. Examples of systemic agents taken for rheumatic conditions include methotrexate, sulfasalazine, and leflunomide; OR

(4) If the patient has plaque psoriasis, the patient is taking the requested agent in combination with phototherapy.

	Note: Examples include narrowband ultraviolet B [NB-UVB] phototherapy; Note: For patients who have not tried the Preferred Products, Cosentyx is approved for patients who meet criterion 4Aiia but do not meet 4Aiia[(1), (2), (3), or (4)]; OR **b)** The patient has AS and has tried TWO of Cosentyx, Enbrel, and Humira [documentation required]. Note: A trial of Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), or Simponi (Aria or SC) also counts towards a trial of [documentation required]; OR **c)**The patient has plaque psoriasis and has tried THREE of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required]; OR **d)** The patient has PsA and has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. **B)** If the patient has met criterion 4Ai (the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria), but criterion 4Aii is not met, offer to review for a Preferred product using the respective *ESI Standard Inflammatory Conditions – PA Policy* criteria: **i.** Patients with AS: Cosentyx, Enbrel, or Humira **ii.** Patients with plaque psoriasis: Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya **iii.** Patients with PsA: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR **5. Other Conditions.** Approve Taltz (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Taltz PA Policy* criteria.
Xeljanz/ Xeljanz XR	**1. Ulcerative Colitis – Initial Therapy.** **A)** Approve the requested agent for 4 months if the patient meets the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Xeljanz/XR PA Policy* criteria; AND **ii.** The patient has tried Humira. Note: A trial of an infliximab product or Simponi SC also counts. **B)** If the patient has met criterion 1Ai (the ESI Standard Inflammatory Conditions – Xeljanz PA Policy criteria), but criterion 1Aii is not met, offer to review for the Preferred product (Humira) using the *ESI Standard Inflammatory Conditions – Humira PA Policy* criteria. **2. Ulcerative Colitis – Patients Currently Taking Xeljanz/XR.** **A)** Approve the requested agent for 1 year if the patient meets BOTH of the following conditions (i and ii): **i.** The patient meets the *ESI Standard Inflammatory Conditions – Xeljanz/Xeljanz XR PA Policy* criteria for Patients Currently taking Xeljanz/Xeljanz XR; AND **ii.** The patient meets ONE of the following conditions (a or b): **a)** The patient has been established on Xeljanz/Xeljanz XR for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz/Xeljanz XR was dispensed within the past 130 days [verification in prescription claims history required] if claims history is not available, according to the prescriber [verification by prescribing physician required]. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Xeljanz/Xeljanz XR for at least 90 days AND the patient has been receiving Xeljanz/Xeljanz XR via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Xeljanz/Xeljanz XR); OR

	b) The patient has UC and has tried Humira. Note: A trial of an infliximab product (e.g., Remicade, Inflectra, Renflexis) or Simponi SC also counts. **B)** If the patient has met criterion 2Ai (the *ESI Standard Inflammatory Conditions – Xeljanz/Xeljanz XR PA Policy* criteria but criterion 2Aii is not met, offer to review for a Preferred product (Humira) using the respective *ESI Standard Inflammatory Conditions – Adalimumab Products PA Policy* criteria. **3. Other Conditions.** Approve Xeljanz/XR (initial therapy for a duration as directed or 1 year for patients continuing therapy) if the patient meets the *ESI Standard Inflammatory Conditions – Xeljanz/XR PA Policy* criteria.

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19. Tremfya injection [prescribing information]. Horsham, PA: Janssen Biotech; October 2017.
20. Xeljanz®/Xeljanz XR tablets/extended release tablets [prescribing information]. New York, NY: Pfizer Inc; December 2017.
21. Ilumya™ subcutaneous injection [prescribing information]. Whitehouse Station, NJ: Sun/Merck; March 2018.
22. Rinvoq [prescribing information]. North Chicago, IL: AbbVie; August 2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
2020 Policy	Changes from the 2019 Policy **Cimzia:** For plaque psoriasis, Cimzia remains Non-Preferred. The patient is now directed to try three of the Preferred Products (previously was two Preferreds). **Stelara SC:** Stelara SC is now Non-Preferred for UC (previously not an approved indication and was not targeted in this policy). The patient is now directed to try Humira prior to Stelara SC. Exceptions apply for patients who have tried another TNFi and to those who have already received Induction with Stelara IV.	12/11/2019
Selected revision	**Xejanz XR:** Due to approval in UC, add Xeljanz XR to Step 2 for UC. Criteria are the same as for Xeljanz and direct the patient to the Preferred Product (Humira).	12/18/2019
Selected revision	**Cimzia:** For plaque psoriasis, move Cimzia to Step 3a, which directs patients to a trial of two Preferred Products (previously, patients were directed to a trial of three Preferred Products).	01/15/2020

APPENDIX A

Table 1. Approved TNFis for Targeted Indications.*

	Rheumatology					Dermatology	Gastroenterology	
	RA	**JIA**	**AS**	**nr-axSpA**	**PsA**	**PsO**	**CD**	**UC**
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Humira	√	√	√	--	√	√	√	√
Inflectra	√	--	√	--	√	√	√	√

Remicade	√	--	√	--	√	√	√	√
Renflexis	√	--	√	--	√	√	√	√
Simponi SC	√	--	√	--	√	--	--	√
Simponi Aria	√	--	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; * Refer to the selected *ESI Inflammatory Conditions Standard Prior Authorization Policies* for the specific patient population approved for each indication; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.*

	Rheumatology				Dermatology	Gastroenterology	
	RA	**JIA**	**AS**	**PsA**	**PsO**	**CD**	**UC**
Cosentyx	--	--	√	√	√	--	--
Ilumya	--	--	--	--	√	--	--
Siliq	--	--	--	--	√	--	--
Skyrizi	--	--	--	--	√	--	--
Stelara SC	--	--	--	√	√	√^	√^
Stelara IV	--	--	--	--	--	√#	√#
Taltz	--	--	--	√	√	--	--
Tremfya	--	--	--	--	√	--	--

IL – Interleukin; * Refer to the selected *ESI Standard Prior Authorization Policies* for the specific patient population approved for each indication; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis; ^ Maintenance dosing only; # Induction dosing only.

Table 3. Other Biologics and tsDMARDs Approved for Targeted Indications.[*]

	Rheumatology				Dermatology	Gastroenterology	
	RA	**JIA**	**AS**	**PsA**	**PsO**	**CD**	**UC**
Actemra IV	√	√[^]	--	--	--	--	--
Actemra SC	√	√[^]	--	--	--	--	--
Kevzara	√	--	--	--	--	--	--
Kineret	√	--	--	--	--	--	--
Olumiant	√	--	--	--	--	--	--
Orencia IV	√	√[#]	--	√	--	--	--
Orencia SC	√	√[#]	--	√	--	--	--
Otezla	--	--	--	√	√	--	--
Rinvoq	√	--	--	--	--	--	--
Rituxan IV	√	--	--	--	--	--	--
Olumiant	√	--	--	--	--	--	--
Xeljanz/XR	√	--	--	√	--	--	--
Xeljanz XR	√	--	--	√	--	--	√

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; [*] Refer to the selected *ESI Standard Prior Authorization Policies* for the specific patient population approved for each indication; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis; IV – Intravenous; [^] Indicated in polyarticular and systemic JIA; [#] Indicated in polyarticular JIA.