

Biologics and Immunologics

HPCPS: See Other Information

LOB:	MCAL
Duration of Approval:	For cytokine release syndrome (CRS) (Actemra, Avtozma, Tyenne): Refer to dosing table For prophylaxis of acute graft versus host disease (aGvHD) (Orencia): One fill up to day 28 post-transplant All other diagnoses: One year
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes (Actemra, Avsola, Cosentyx, Entyvio, Ilumya, Inflectra, Orencia, Remicade, Renflexis, Simponi Aria, Skyrizi, Stelara, Tremfya)
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

- **Actemra (tocilizumab):** Has intravenous (IV) and subcutaneous (SQ) dosing options for rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA) and systemic juvenile idiopathic arthritis (SJIA)
- **Avsola (infliximab-axxq)**
- **Avtozma (tocilizumab-anoh):** Has IV and SQ dosing options for RA, GCA, PJIA and SJIA
- **Cosentyx (secukinumab):** Has IV and SQ dosing options for ankylosing spondylitis (AS), psoriatic arthritis (PsA) and nonradiographic axial spondyloarthritis (nr-axSpA)
- **Entyvio (vedolizumab)**
- **Ilumya (tildrakizumab):** Is given SQ and must be administered by health care provider
- **Imuldosa (ustekinumab-srlf):** Is given IV for induction followed by SQ maintenance for Crohn's disease and ulcerative colitis (UC)
- **Remicade (infliximab)**
- **Inflectra (infliximab-dyyb)**
- **OmvoH (mirikizumab-mrkz):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Orencia (abatacept):** Has IV and SQ dosing options for RA, PsA and PJIA. There is also an optional IV loading dose when using SQ dosing for RA
- **Otulfi (ustekinumab-aaaz):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Pyzchiva (ustekinumab-ttwe):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Renflexis (infliximab-abda)**
- **Selarsdi (ustekinumab-aekn):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Simponi Aria (golimumab)**
- **Skyrizi (risankizumab):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Starjemza (ustekinumab-hmvy):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Stelara (ustekinumab):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Steqeyma (ustekinumab-stba):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Tofidence (tocilizumab-bavi)**
- **Tremfya (guselkumab):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Tyenne (tocilizumab-aazg):** Has IV and SQ dosing options for RA, GCA, PJIA and SJIA
- **Wezlana (ustekinumab-auub):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC
- **Yesintek (ustekinumab-kfce):** Is given IV for induction followed by SQ maintenance for Crohn's disease and UC

PA CRITERIA FOR APPROVAL:

*****All diagnoses that are indicated for SQ dosing only (and self-administration is acceptable) should be reviewed by Medi-Cal Rx as a pharmacy benefit*****

New Therapy

1. The member has a diagnosis for a Food and Drug Administration (FDA)-approved indication (refer to package insert under References) **OR** a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication
AND

2. The medication was prescribed by a rheumatologist, dermatologist, gastroenterologist (GI), ophthalmologist, oncologist/hematologist or transplant specialist **AND**
3. For all diagnoses **EXCEPT** Crohn's disease and ulcerative colitis, the member will not be on concurrent therapy with other biologics **AND**
4. **For diagnosis of rheumatoid arthritis (for Actemra, Avtozma, Tofidence, Tyenne, Cosentyx [off-label], Remicade, Avsola, Inflectra, Renflexis, Orencia, Simponi Aria):** ALL of the following are met (a–c):
 - a. The member has a history of failure, contraindication or reasons for intolerance to one disease-modifying antirheumatic drug (DMARD) agent such as methotrexate, leflunomide, hydroxychloroquine or sulfasalazine.
 - b. **For Actemra, Avtozma, Tofidence or Tyenne:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Enbrel, Humira, Olumiant, Rinvoq, Simponi, Simponi Aria, Xeljanz, Xeljanz XR, Remicade, infliximab, Avsola, Inflectra or Renflexis (**Note:** For diagnosis of RA, Orencia has an optional IV loading dose when using as SQ dosing. Xeljanz/Xeljanz XR are PA required under Medi-Cal Rx)
 - c. **For Orencia or Cosentyx:** The member has a history of failure, contraindication or reasons for intolerance to two of the following: adalimumab biosimilars, Enbrel, Humira, Olumiant, Rinvoq, Simponi, Simponi Aria, Xeljanz, Xeljanz XR, Rituximab, Remicade, infliximab, Avsola, Inflectra, Renflexis, Actemra, Avtozma, Tofidence or Tyenne. (**Note:** Xeljanz/Xeljanz XR are PA required under Medi-Cal Rx)

OR

5. **For diagnosis of psoriatic arthritis (for Cosentyx, Orencia, Remicade, Avsola, Inflectra, Renflexis, Simponi Aria):** ALL of the following are met (a–c):
 - a. **For peripheral arthritis (affecting the hands, wrists, elbows, knees, ankles and feet):** The member has a history of failure, contraindication or reasons for intolerance to one DMARD such as methotrexate, leflunomide or sulfasalazine (**Note:** DMARDs have compendia-supported off-label use for psoriatic arthritis).
 - b. **For axial arthritis (affecting the spine, back, hips):** The member has a history of failure, contraindication or reasons for intolerance to one oral nonsteroidal anti-inflammatory drugs (NSAIDs) such as celecoxib, diclofenac, ibuprofen, indomethacin, meloxicam, nabumetone, piroxicam or sulindac (**Note:** NSAIDs have off-label use for psoriatic arthritis based on peer-reviewed literature)
 - c. **For Cosentyx or Orencia:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Enbrel, Humira, Otezla, Otezla XR, Rinvoq, Rinvoq LQ, Simponi, Simponi Aria, Sotyktu, Xeljanz, Xeljanz XR, Remicade, infliximab, Avsola, Inflectra or Renflexis (**Note:** Xeljanz/Xeljanz XR and Sotyktu are PA-required under Medi-Cal Rx)

OR

6. **For diagnosis of PJIA (for Actemra, Avtozma, Tofidence, Tyenne, Orencia, Remicade [off-label], Avsola [off-label], Inflectra [off-label], Renflexis [off-label], Simponi Aria):** ALL of the following are met (a–b):
 - a. The member has a history of failure, contraindication or reasons for intolerance to one other systemic therapy such as DMARD agents (e.g., methotrexate, leflunomide [off-label] or sulfasalazine) or NSAIDs (e.g., celecoxib, etodolac, ibuprofen [off-label], meloxicam or naproxen).
 - b. **For Actemra, Avtozma, Orencia, Tofidence or Tyenne:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Enbrel, Humira, Rinvoq, Rinvoq LQ, Simponi Aria or Xeljanz (**Note:** Xeljanz is PA required under Medi-Cal Rx)

OR

7. **For diagnosis of SJIA (for Actemra, Avtozma, Tofidence, Tyenne, Remicade [off-label], Avsola [off-label], Inflectra [off-label], Renflexis [off-label]):** ALL of the following are met (a–b):

- a. The member has a history of failure, contraindication or reasons for intolerance to one other systemic therapy such as NSAIDs (e.g., celecoxib, etodolac, ibuprofen [off-label], meloxicam [off-label] or naproxen [off-label]) or corticosteroids (e.g., prednisone, methylprednisolone or prednisolone)
- b. **For Actemra or Tofidence:** The member has a history of failure, contraindication or reasons for intolerance to Avtozma or Tyenne

OR

8. **For diagnosis of ankylosing spondylitis (AS) (for Cosentyx, Remicade, Avsola, Inflectra, Renflexis, Simponi Aria):**
 - a. **For Cosentyx:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Cimzia, Enbrel, Humira, Rinvoq, Simponi, Simponi Aria, Xeljanz, Xeljanz XR, Remicade, infliximab, Avsola, Inflectra or Renflexis (**Note:** Xeljanz/Xeljanz XR are PA-required under Medi-Cal Rx)

OR

9. **For diagnosis of nr-axSpA (for Cosentyx):** The member has a history of failure, contraindication or reasons for intolerance to one of the following: Cimzia, Rinvoq, adalimumab biosimilars (off-label) or Humira (off-label)

OR

10. **For diagnosis of plaque psoriasis (for Ilumya, Remicade, Avsola, Inflectra, Renflexis): ALL** of the following are met **(a–b)**:
 - a. The member has **ONE** of the following:
 - 1) Psoriatic lesions $\geq 10\%$ of body surface area (BSA)
 - 2) Psoriatic lesions affecting the hands, feet, face or genital area
 - 3) Psoriatic lesions involving $\geq 3\%$ of BSA, and the member has a history of failure, contraindication or reasons for intolerance to **ONE** or more of the following:
 - a) Immunosuppressive treatments (such as cyclosporine [off-label] or methotrexate)
 - b) Photochemotherapy (i.e., psoralen plus ultraviolet A therapy)
 - c) Phototherapy (i.e., ultraviolet light A [PUVA], ultraviolet light B [UVB])
 - d) Topical agents (such as anthralin, calcipotriene, coal tars, corticosteroids [e.g., triamcinolone, fluocinonide, betamethasone, desonide, mometasone], tazarotene)
 - b. **For Ilumya:** Member has a history of failure, contraindication or reasons for intolerance to two of the following: adalimumab biosimilars, Enbrel, Humira, Otezla, Otezla XR, Sotyktu, Taltz, Remicade, infliximab, Avsola, Inflectra, or Renflexis (**Note:** Sotyktu is PA required under Medi-Cal Rx)

OR

11. **For diagnosis of Crohn's disease (for Entyvio, Remicade, Avsola, Inflectra, Renflexis, Omvoh, Skyrizi, Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek, Tremfya): ALL** of the following are met **(a–b)**:
 - a. **For Entyvio, Imuldosa, Omvoh, Otulfi, Selarsdi, Skyrizi, Tremfya or Yesintek:** Member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Cimzia, Humira, Pyzchiva, Rinvoq, Starjemza, Stelara, Steqeyma, Wezlana, Remicade, infliximab, Avsola, Inflectra or Renflexis (**Note:** Recommended induction dose is IV followed by SQ maintenance dosing for the following drugs: Skyrizi, Stelara, Imuldosa/Otulfi/Pyzchiva/Selarsdi/Starjemza/Steqeyma/Wezlana/Yesintek)
 - b. **If request is for combination therapy with two biologic agents:** ALL of the following are met **(1–2)**:
 - 1) Both biologic agents have different mechanisms of action
 - 2) The member has failed monotherapy with a biologic agent

OR

12. **For diagnosis of ulcerative colitis (for Entyvio, Remicade, Avsola, Inflectra, Renflexis, Omvoh, Skyrizi, Stelara, Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek, Tremfya) ALL of the following are met (a–b):**

- a. **For Entyvio, Imuldosa, Omvoh, Otulfi, Selarsdi, Skyrizi, Tremfya or Yesintek:** Member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Humira, Pyzchiva, Rinvoq, Simponi, Starjemza, Stelara, Steqeyma, Wezlana, Xeljanz, Xeljanz XR, Remicade, infliximab, Avsola, Inflectra or Renflexis (**Note:** Recommended induction dose is IV followed by SQ maintenance dosing for the following drugs: Skyrizi, Stelara, Imuldosa/Otulfi/Pyzchiva/Selarsdi/Starjemza/Steqeyma/Wezlana/Yesintek. Xeljanz/Xeljanz XR are PA required under Medi-Cal Rx)
- b. **If the request is for combination therapy with two biologic agents:** ALL of the following are met (1–2):
 - 1) Both biologic agents have different mechanisms of action
 - 2) The member has failed monotherapy with a biologic agent

OR

13. **For diagnosis of hidradenitis suppurativa (for Remicade [biosimilars: Avsola, Inflectra, Renflexis [off-label], Stelara [biosimilars: Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Steqeyma, Wezlana, Yesintek [off-label]]): ALL of the following are met (a–c):**

- a. Documentation in chart notes confirming moderate to severe disease with Hurley Stage II or Hurley Stage III
- b. The member has a history of failure, contraindication or reasons for intolerance to one of the following: adalimumab biosimilars, Bimzelx, Cosentyx or Humira
- c. **For Imuldosa, Otulfi, Selarsdi, Yesintek:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: Avsola, Inflectra, Pyzchiva, Remicade, Renflexis, Stelara, Starjemza, Steqeyma or Wezlana

OR

14. **For diagnosis of uveitis (for Actemra [biosimilars: Avtozma, Tofidence, Tyenne [off-label], Remicade [biosimilars: Avsola, Inflectra, Renflexis [off-label]]): ALL of the following are met (a–c):**

- a. The member has a history of failure, contraindication or reasons for intolerance to ophthalmic (topical/periorcular) corticosteroids (such as difluprednate, dexamethasone, fluocinolone, fluorometholone, methylprednisolone, prednisolone, triamcinolone) or systemic corticosteroids (such as prednisone, prednisolone, methylprednisolone)
- b. The member has a history of failure, contraindication or reasons for intolerance to adalimumab biosimilars or Humira
- c. **For Actemra, Avtozma, Tofidence or Tyenne:** The member has a history of failure, contraindication or reasons for intolerance to one of the following: Avsola, Inflectra, Remicade or Renflexis

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication was prescribed by a rheumatologist, dermatologist, gastroenterologist (GI), ophthalmologist, oncologist/hematologist or transplant specialist **AND**
3. **For all diagnoses:** Documentation provided showing positive response to therapy **AND**
4. **For all diagnoses EXCEPT Crohn's disease and ulcerative colitis,** the member will not be on concurrent therapy with other biologics

DOSAGE & ADMINISTRATION

Drug	Recommended Dosing
Actemra	Uveitis (off-label)

Biologics and Immunologics

HCPCS: See Other Information

Drug	Recommended Dosing
Avtozma Tofidence Tyenne	4–8 mg/kg IV every four weeks CRS (For Actemra, Avtozma, Tyenne) (Weight < 30 kg): 12 mg/kg IV infusion; (weight ≥ 30 kg): 8 mg/kg IV infusion - If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to three additional doses may be administered. The interval between consecutive doses should be at least eight hours.
Cosentyx	RA (off-label) 10 mg/kg IV at weeks 0, 2 and 4, followed by 150 mg SQ every four weeks
Inflectra Renflexis Avsola Remicade	PJIA (off-label) 3 mg/kg IV at weeks 0, 2 and 6, followed by 3–6 mg/kg IV every eight weeks thereafter SJIA (off label) 3 mg/kg IV at weeks 0, 2 and 6, followed by 3 mg/kg IV every eight weeks thereafter Hidradenitis Suppurativa (off-label) - Usually completed in two to four infusions: 5 mg/kg IV at weeks 0, 2 and 6 OR 5 mg/kg IV and repeat four to six weeks after first infusion Uveitis (off-label) 3–5 mg/kg IV at weeks 0, 2 and 6 and every four to eight weeks thereafter OR 3–6 mg/kg IV at weeks 2, 4 and 6 and every two to eight weeks thereafter
Stelara Imuldosa Otulfi Pyzchiva Selarsdi Starjemza Steqeyma Wezlana Yesintek	Hidradenitis Suppurativa (off-label) (Weight ≤ 55 kg): Induction 260 mg IV x one dose; Maintenance: 90 mg SQ Q12 weeks (Weight >55 to 85 kg): Induction 390 mg IV x one dose; Maintenance: 90 mg SQ Q12 weeks (Weight > 85 kg): Induction 520 mg IV x one dose; Maintenance: 90 mg SQ Q12 weeks

OTHER INFORMATION:

HCPCS	Description	Brand name
J3262	Injection, tocilizumab, 1 mg	Actemra
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg	Avsola
Q5156	Injection, tocilizumab-anoh, biosimilar, 1 mg	Avtozma
J3590	Unclassified biologics	Cosentyx (SC)
J3247	Injection, secukinumab, IV, 1 mg	Cosentyx (IV)
J3380	Injection, vedolizumab, 1 mg	Entyvio
J3245	Injection, tildrakizumab, 1mg	Ilumya
Q5098	Injection, ustekinumab-srlf, biosimilar, 1 mg	Imuldosa
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg	Inflectra
J2267	Injection, mirikizumab-mrkz, 1 mg	Omvoh
J0129	Injection, abatacept, 10 mg	Orencia
Q9999	Injection, ustekinumab-aaaz (otulfi), biosimilar, 1 mg	Otulfi
Q9996	Injection, ustekinumab-ttwe (Pyzchiva), subcutaneous, 1 mg	Pyzchiva (SC)
Q9997	Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg	Pyzchiva (IV)
J1745	Injection, infliximab, 10 mg	Remicade
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg	Renflexis
Q9998	Injection, ustekinumab-aekn (Selarsdi), 1 mg	Selarsdi

Biologics and Immunologics

HCPCS: See Other Information

HCPCS	Description	Brand name
J1602	Injection, golimumab, 1 mg (IV)	Simponi Aria (IV)
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	Skyrizi (IV)
J3590	Unclassified biologics	Skyrizi (SC)
J3357	ustekinumab, for subcutaneous injection, 1 mg	Stelara (SC)
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg	Starjemza (SC), (IV)
J3358	ustekinumab, for intravenous, 1 mg	Stelara (IV)
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg	Steqeyma (SC), (IV)
Q5133	Injection, tocilizumab-bavi, biosimilar, 1 mg	Tofidence
J1628	Injection, guselkumab, 1 mg	Tremfya
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	Tyenne
Q5137	Injection, ustekinumab-auub (Wezlana), biosimilar, SC, 1 mg	Wezlana (SC)
Q5138	Injection, ustekinumab-auub (Wezlana), biosimilar, IV, 1 mg	Wezlana (IV)
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg	Yesintek (SC), (IV)

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2. Avsola Prescribing Information. www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Avsola/avsola_pi_english.pdf. 09/2025.
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P&T APPROVAL HISTORY

1. August 2016 P&T Drug Review
2. August 2017 P&T Drug Review
3. November 2018 P&T Drug Review
4. February 2019 P&T Drug Review
5. November 2019 P&T Drug Review
6. August 2021 P&T Drug Review
7. May 2024 P&T Drug Review

UMC REVIEW:

6/2026