PARTNERSHIP HEALTHPLAN of CALIFORNIA
A Public Agency

**Partnership Medi-Cal**
**Effective: October 1st, 2025**

# P & T: July 10th, 2025

**Approved New & Revised PA Criteria:**

**Brand/Trade names are shown for reference purposes only**. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per Partnership HealthPlan of California Policy #MPRP4033.

1. Requirements for Subcutaneous Guselkumab (Tremfya™)
2. Requirements for Intravenous Guselkumab (Tremfya™)
3. Requirements for Fluocinolone Intravitreal Implant (Iluvien™)
4. Requirements for Fluocinolone Implant (Yutiq™)
5. Requirements for Fluocinolone Implant (Retisert™)
6. Requirements for Ranibizumab (Lucentis™) Intravitreal Injection
7. Requirements for Ranibizumab-eqrn (Cimerli™) Intravitreal Injection
8. Requirements for Ranibizumab-nuna Intravitreal Injection (Byooviz™)
9. Requirements for Ranibizumab Intravitreal Injection via Sustained Intravitreal Implant (Susvimo™)
10. Requirements for Brolucizumab-dbll Intravitreal Injection (Beovu™)
11. Requirements for Intravitreal Aflibercept (Eylea™), Aflibercept-ayyh (Pavblu™), Aflibercept-abzv (Enzeevu™), Aflibercept-mrbb (Ahzantive™), and Alfibercept-yzvy (Opuviz™)
12. Requirements for Faricimab Intravitreal Injection (Vabysmo™)
13. Requirements for Revakinagene Taroretcel-lwey (Encelto™)
14. Requirements for Pegcetacoplan (Syfovre™)
15. Requirements for Avacincaptad Pegol (Izervay™)
16. Requirements for Romosozumab-aqqg SC Injection (Evenity™)
17. Requirements for Teplizumab-mzwv (Tzield™)
18. Requirements for mirikizumab-mrkz (Omvoh™)
19. Requirements for Intravenous Risankizumab-rzaa (Skyrizi™)
20. Requirements for IV Ustekinumab (Stelara™) and biosimilars Ustekinumab-auub (Wezlana™), -ttwe (Pyzchiva™), -aekn (Selarsdi™), -aauz (Otulfi™), -srlf (Imuldosa™), -stba (Steqeyma™), -kfce (Yesintek™), (IV products only)
21. Requirements for Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™)
22. Requirements for Intravenous Nipocalimab-aahu (Imaavy™)
23. Requirements for Rozanolixizumab-noli (Rystiggo™)
24. Requirements for Remestemcel-L-rknd (Ryoncil™)
25. Requirements for Intravenous Axatilimab (Niktimvo™)
26. Requirements for Inebilizumab-cdon (Uplizna™)
27. Requirements for Esketamine Nasal Spray (Spravato™)

# Requirements for Subcutaneous Guselkumab (Tremfya™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Moderate to severe plaque psoriasis (PSO)<br>2) Active psoriatic arthritis (PsA)<br>3) Moderately to severely active ulcerative colitis (UC)<br>4) Moderately to severely active Crohn's disease (CD)<br><br>*Note: please see Requirements for Intravenous Guselkumab (Tremfya) for criteria for IV induction dosing for Crohn's Disease and Ulcerative Colitis.* |
| **Exclusion Criteria** | • Active, serious infection, latent (untreated) tuberculosis<br>• Combination with another monoclonal antibody/biologic therapy |
| **Required Medical Information** | For all indications:<br>1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated).<br>2) Treatment plan.<br>3) Disease Activity Score.<br>4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test).<br>5) Reason(s) why the member is unable to obtain from a pharmacy for self-administration.<br><br>Active PSO:<br>1) Documented therapeutic failure after a minimum 3-month trial of (or contraindication to) a TNFI: adalimumab (Humira), etanercept (Enbrel), or certolizumab (Cimzia). *Note that at least one of (a, b, or c) is required for TNFi approval:*<br>a. Documentation of ≥ 10% BSA affected OR<br>b. Documentation of <10% BSA affecting sensitive areas (palms of hands, soles of feet, head/neck, genitalia), OR<br>c. Therapeutic failure after a 3-month trial of 2 or more non-biologic therapies (unless contraindicated):<br>i. Methotrexate<br>ii. Cyclosporin<br>iii. Acitretin (TAR required)<br>iv. Phototherapy in conjunction with methoxsalen (TAR required)<br><br>Active PsA:<br>1) Rheumatology clinic notes to confirm diagnosis of PsA AND<br>2) Severe psoriatic arthritis with erosive disease and functional limitation or<br>3) Moderate to severe axial involvement or<br>4) Documented therapeutic failure after a minimum of a 3-month trial of (or contraindication to) at least one each from a (DMARD) and b (TNFi):<br>a. Methotrexate, or other oral DMARD if member is unable to take methotrexate, AND<br>b. TNFi: Adalimumab (Humira), etanercept (Enbrel), subcutaneous golimumab (Simponi), or certolizumab (Cimzia). |

# Requirements for Subcutaneous Guselkumab (Tremfya™)

| | |
|---|---|
| | Moderately to severely active UC (maintenance dosing) or CD (induction or maintenance dosing)<br>1) Documentation of trial and failure to both of the following (a AND b)<br>a. TNF inhibitor (TNFi): adalimumab, infliximab (Inflectra™-preferred PA group 1) (Avsola™, Renflexis™-PA group 2), certolizumab (CD indication only) or subcutaneous golimumab (UC indication only)<br>b. Ustekinumab. |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | PSO: Dermatologist<br>PsA: Rheumatologist (prescribed or recommend by); a dermatologist may continue treatment that was initiated based on a rheumatologist's recommendation. |
| **Coverage Duration** | Case-dependent (medical office single dose requested vs outpatient hospital with multiple doses requested). Limited to the number of doses needed until the member is able to resume self-administration at home. |
| **Other Requirements & Information** | This medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled *Standard Requirements for Self-Administered Drugs.*<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J1628 | Injection, Guselkumab, 1 mg (subcutaneous product only) | Subcutaneous<br>• PSO & PsA, 100 mg at week 0, 4 and then every 8 weeks.<br>• CD Induction: 400mg on weeks 0, 4, and 8.<br>• CD & UC Maintenance:100 mg at week 16 and every 8 weeks thereafter OR 200mg at week 12 and every 4 weeks thereafter. |

# Requirements for Intravenous Guselkumab (Tremfya™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Moderately to severely active ulcerative colitis (UC)<br>2) Moderately to severely active Crohn's disease (CD)<br><br>*Note: please see Requirements for Subcutaneous Guselkumab (Tremfya) for criteria for plaque psoriasis, psoriatic arthritis, and maintenance dosing for UC and CD.* |
| **Exclusion Criteria** | • Active, serious infection, latent (untreated) tuberculosis<br>• Combination with another monoclonal antibody/biologic therapy |
| **Required Medical Information** | 1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated).<br>2) Treatment plan.<br>3) Disease Activity Score.<br>4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test).<br>5) Documentation of trial and failure to both of the following (a AND b)<br>a. TNF inhibitor (TNFi): adalimumab, infliximab (Inflectra™-preferred PA group 1) (Avsola™, Renflexis™-PA group 2), certolizumab (CD indication only) or subcutaneous golimumab (UC indication only)<br>b. Ustekinumab.<br>6) For Crohn's Disease: reasons why Subcutaneous Guselkumab (Tremfya) cannot be used for induction dosing. |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Prescribed or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial (induction dosing): 3 doses (8 weeks) |
| **Other Requirements & Information** | Following IV induction this medication is typically self-administered by the member or a caregiver at home. See the additional TAR requirements in the document titled *Standard Requirements for Self-Administered Drugs.*<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Intravenous Guselkumab (Tremfya™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J1628 | Injection, Guselkumab, 1 mg (intravenous product only) | Intravenous:<br>• CD Induction: 200 mg at week 0, 4, and 8 OR 400mg at week 0, 4, and 8, transitioning to subcutaneous at week 12 or 16.<br>• UC Induction: 200 mg at week 0, 4, and 8, transitioning to subcutaneous at week 12 or 16. |

# Requirements for Fluocinolone Intravitreal Implant (Iluvien™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | • Treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure (IOP).<br>• The treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. |
| **Exclusion Criteria** | • Active or suspected ocular or periocular infection (viral, bacterial or fungal) of the cornea and conjunctiva<br>• Glaucoma with cup to disc ratios of greater than 0.8<br>• Use in combination with another corticosteroid implant/insert/injection |
| **Required Medical Information** | Clinic notes to include:<br>1) Documentation to confirm diagnosis submitted<br>2) Cup to disc ratio (C/D) <0.8<br>3) Prior treatments (if any) that have been tried<br>4) Baseline intraocular pressure (IOP)<br>5) Documentation of trial of the following products without any significant rise in IOP:<br>a. Dexamethasone implant (Ozurdex™) (TAR required), can last up to 6 months OR<br>b. Triamcinolone intravitreal injection (Triesence™)) (No TAR required), can last for up to 6 months |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Limit to 1 implant per 36 months |
| **Other Requirements & Information** | Renewal criteria, dependent on positive clinical response:<br>• Improvement compared to baseline for:<br>o Current BCVA score or similar visual acuity assessment.<br>o Current IOP<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Fluocinolone Intravitreal Implant (Iluvien™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J7313 | Intravitreal fluocinolone implant (Iluvien™), 0.01mg | One 0.19 mg implant injected intravitreally in affected eye |

# Requirements for Fluocinolone Implant (Yutiq™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of chronic, noninfectious uveitis affecting the posterior segment of the eye (Choroiditis). |
| **Exclusion Criteria** | • Active or suspected ocular or periocular infection (viral, bacterial or fungal) of the cornea and conjunctiva<br>• Use in combination with another corticosteroid implant/insert/injection |
| **Required Medical Information** | Clinic notes that document all of the following:<br>1) Estimated duration of 3 months or more (chronic) and confirmation of posterior segment uveitis<br>2) Prior treatment (if any) that have been tried<br>3) Baseline visual acuity from baseline best corrected visual acuity(BCVA) score or similar visual acuity assessment.<br>4) Baseline intraocular pressure (IOP)<br>5) Documentation of trial of the following products without any significant rise in IOP: Dexamethasone implant (Ozurdex™) (TAR required) OR triamcinolone intravitreal injection (Triesence™) both can last up to 6 months |
| **Age Restriction** | Yutiq™: 18 years and older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Limited to 1 implant per 36 months |
| **Other Requirements & Information** | Renewal criteria, dependent on positive clinical response:<br>• Improvement compared to baseline for:<br>  ○ Current BCVA score or similar visual acuity assessment.<br>  ○ Current IOP<br>• Date of last intravitreal implant.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Fluocinolone Implant (Yutiq™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| Product | HCPCS | Description | Dosing, Units |
|---|---|---|---|
| Yutiq | J7314 | Intravitreal fluocinolone implant (Yutiq™), 0.01 mg | One 0.18 mg implant injected intravitreally in affected eye. |

# Requirements for Fluocinolone Implant (Retisert™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of chronic, noninfectious uveitis affecting the posterior segment of the eye (Choroiditis). |
| **Exclusion Criteria** | • Active or suspected ocular or periocular infection (viral, bacterial or fungal) of the cornea and conjunctiva<br>• Use in combination with another corticosteroid implant/insert/injection |
| **Required Medical Information** | Clinic notes that document all of the following:<br>1) Estimated duration of 3 months or more (chronic) and confirmation of posterior segment uveitis<br>2) Prior treatment (if any) that have been tried<br>3) Baseline visual acuity from baseline best corrected visual acuity(BCVA) score or similar visual acuity assessment.<br>4) Baseline intraocular pressure (IOP)<br>5) Documentation of trial of the following products without any significant rise in IOP:<br>a. Dexamethasone implant (Ozurdex™) (TAR required) OR triamcinolone intravitreal injection (Triesence™) both can last up to 6 months AND<br>b. A trial of or reason(s) why fluocinolone implant Yutiq™ or Iluvien™ cannot be used. |
| **Age Restriction** | 12 years and older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Limited to 1 implant per 30 months |
| **Other Requirements & Information** | Renewal criteria, dependent on positive clinical response:<br>• Improvement compared to baseline for:<br>○ Current BCVA score or similar visual acuity assessment.<br>○ Current IOP<br>• Date of last intravitreal implant.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Fluocinolone Implant (Retisert™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| Product | HCPCS | Description | Dosing, Units |
|---|---|---|---|
| Retisert | J7311 | Intravitreal fluocinolone implant (Retisert™), 0.01 mg | One 0.59 mg implant injected intravitreally in affected eye. |

# Requirements for Ranibizumab (Lucentis™) Intravitreal Injection

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Diabetic macular edema (DME)<br>2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME)<br>3) Neovascular (wet) age-related macular degeneration (AMD)<br>4) Macular edema following retinal vein occlusion (RVO)<br>5) Myopic Choroidal Neovascularization (mCNV) |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | 1) Clinic notes to confirm the diagnosis submitted<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR) |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist |
| **Coverage Duration** | Limited to a maximum of 13 injections per 12 months (per eye). |
| **Other Requirements** | Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested).<br><br>Baseline and updated vision status maybe requested with evidence of:<br>1) Improvement or stabilization compared to baseline or<br>2) Decrease in rate of vision loss compared to baseline<br><br>For members on Susvimo intravitreal implant, requiring additional ranibizumab doses:<br>Documentation supporting the medical necessity of supplemental doses must include at least one of the following:<br>1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR<br>2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR<br>3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo<br><br>Requests for off-label use: See Partnership criteria document, *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Ranibizumab (Lucentis™) Intravitreal Injection

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2778 | Intravitreal injection, ranibizumab, per 0.1 mg | AMD, RVO, mCNV: 0.5mg (5units) every 28 days<br><br>DME/DR w/DME, PDR: 0.3mg (3 units) every 28 days |

# Requirements for Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Diabetic macular edema (DME)<br>2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME)<br>3) Neovascular (wet) age-related macular degeneration (AMD)<br>4) Macular edema following retinal vein occlusion (RVO)<br>5) Myopic Choroidal Neovascularization (mCNV) |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | 1) Clinic notes to confirm the diagnosis submitted<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR)<br>4) Documentation of trial and failure to, or reason(s) why preferred ranibizumab product, Lucentis, cannot be used |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist |
| **Coverage Duration** | Limited to a maximum of 13 injections per 12 months (per eye). |
| **Other Requirements** | Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested).<br><br>Baseline and updated vision status maybe requested with evidence of:<br>1) Improvement or stabilization compared to baseline or<br>2) Decrease in rate of vision loss compared to baseline<br><br>For members on Susvimo intravitreal implant, requiring additional ranibizumab doses:<br>Documentation supporting the medical necessity of supplemental doses must include at least one of the following:<br>1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR<br>2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR<br>3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo<br><br>Requests for off-label use: See Partnership criteria document, *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Ranibizumab-eqrn (Cimerli™) Intravitreal Injection

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| Q5128 | Intravitreal injection, ranibizumab-eqrn (cimerli), per 0.1 mg | AMD, RVO, mCNV: 0.5mg (5units) every 28 days<br><br>DME/DR w/DME, PDR: 0.3mg (3 units) every 28 days |

# Requirements for Ranibizumab-nuna Intravitreal Injection (Byooviz™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Neovascular (wet) age-related macular degeneration (AMD)<br>2) Macular edema following retinal vein occlusion (RVO)<br>3) Myopic Choroidal Neovascularization (mCNV) |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | 1) Clinic notes confirming the submitted diagnosis<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR)<br>4) Documentation of trial and failure to, or reason(s) why preferred ranibizumab product, Lucentis, cannot be used |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Must be prescribed or recommended by an Ophthalmologist. |
| **Coverage Duration** | Limited to a maximum of 13 injections per 12 months (per eye). |
| **Other Requirements** | Renewal authorizations will be based on documentation of benefit from therapy (may be indicated on the TAR unless clinic notes are specifically requested). Baseline and updated vision status maybe requested with evidence of:<br>1) Improvement or stabilization compared to baseline OR<br>2) Decrease in rate of vision loss compared to baseline<br><br>For members on Susvimo intravitreal implant, requiring additional ranibizumab doses:<br>Documentation ~~of~~ supporting the medical necessity of supplemental doses must include at least one of the following:<br>1) A decrease of 15 ETDRS letters or more from the best recorded visual acuity score (BCV) A at baseline/since starting Susvimo, OR<br>2) An increase of 150 mm or more in retinal thickness measured by central subfield thickness (CST) on spectral-domain OCT (SD OCT) from the lowest CST measurement since starting Susvimo, OR<br>3) An increase of 100 mm or more in CST on SD OCT from the lowest CST measurement since starting Susvimo associated with a decrease of 10 ETDRS letters or more from the best recorded BCVA at baseline/since starting Susvimo<br><br>Requests for off-label use: See Partnership criteria document, *Case-by-Case TAR Requirements and Considerations* |

# Requirements for Ranibizumab-nuna Intravitreal Injection (Byooviz™)

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| Q5124 | Injection, ranibizumab-nuna, 0.1 mg | 0.5ml every 28 days<br><br>nAMD: treatment interval may be extended after the initial 4 doses. |

# Requirements for Ranibizumab Intravitreal Injection via Sustained Intravitreal Implant (Susvimo™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | • Neovascular (wet) age-related macular degeneration (AMD)<br>• Diabetic Macular Edema (DME)<br>• Diabetic Retinopathy (DR) |
| **Exclusion Criteria** | • Members with active ocular or periocular infection<br>• Concurrent use of other ophthalmic VEGF inhibitors, with the exception of supplemental ranibizumab & biosimilars (Byooviz™, Lucentis™, Cimerli™) |
| **Required Medical Information** | All Indications:<br>1) Clinic notes to confirm the diagnosis submitted<br>2) Documentation of at least 2 prior doses of intravitreal injections of a VEGF inhibitor with demonstrated anatomic and visual response:<br>• Central subfield thickness (CST) reduction<br>• Improvement in visual acuity from baseline<br>3) Documentation of reasons why a preferred extended dosing interval products cannot be used: aflibercept hd (Eylea HD™) or faricimab-svoa (Vabysmo™) (A TAR is also required for both products) |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist. |
| **Coverage Duration** | Initial approval and renewal: 6 months (1 implant fill). |
| **Other Requirements** | Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested). Baseline and updated vision status may be requested with evidence of:<br>1) Improvement or stabilization compared to baseline or<br>2) Decrease in rate of vision loss compared to baseline<br><br>Requests for off-label use: See Partnership criteria document, *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2779 | Injection, ranibizumab, via intravitreal implant (Susvimo), 0.1 mg | 2 mg every 6 months.<br><br>Maximum treatment dose reimbursed is 20 units (2 mg) per eye every 6 months, and waste should be billed separately per PHC Policy MPRPR4062, Drug Wastage Payments. Maximum authorized TAR units per eye: 100 units, equivalent to 10 mg vials (allowing 2 mg dose + 8 mg waste). |

# Requirements for Brolucizumab-dbll Intravitreal Injection (Beovu™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Neovascular (wet) age-related macular degeneration (AMD)<br>2) Diabetic Macular Edema |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | 1) Clinic notes to confirm the diagnosis submitted<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR) |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist. |
| **Coverage Duration** | Initial: Up to 8 injections per eye in 12 months<br>Renewal: Up to 7 injections per eye in 12 months |
| **Other Requirements** | Renewal will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested).<br>Baseline and updated vision status may be requested with evidence of:<br>1) Improvement or stabilization compared to baseline or<br>2) Decrease in rate of vision loss compared to baseline<br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J0179 | Injection, brolucizumab- dbll, 1mg | nAMD: 6mg every 4 weeks for 3 doses, then every 8-12 weeks.<br><br>DME: 6 mg every 6 weeks for 5 doses, then every 8-12 weeks. |

# Requirements for Intravitreal Aflibercept (Eylea™), Aflibercept-ayyh (Pavblu™), Aflibercept-abzv (Enzeevu™), Aflibercept-mrbb (Ahzantive™), and Alfibercept-yzvy (Opuviz™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA approved indications per product (not all biosimilars are approved for all conditions):<br>1) Diabetic macular edema (DME)<br>2) Diabetic retinopathy in patients with DME (DR w/ DME); or proliferative DR without DME (PDR, +/- DME)<br>3) Neovascular (wet) age-related macular degeneration (AMD)<br>4) Macular edema following retinal vein occlusion (RVO)<br>5) Retinopathy of prematurity (ROP) |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | <u>Diagnosis of AMD, macular edema following RVO, DME/DR+DME, or PDR:</u><br>1) Clinic notes to confirm the diagnosis submitted<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR)<br><br><u>Diagnosis of ROP:</u><br>1) Must have a or b:<br>a. Gestational age of ≤ 32 weeks<br>b. Maximum birth weight of ≤ 1500 g (3.3 lb)<br>2) Must have diagnosis of a, b or c:<br>a. ROP Zone I stage 1+, 2+, 3, & 3+<br>b. ROP Zone II Stage 2+, 3+<br>c. AP-ROP (aggressive posterior ROP)<br>3) Documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR) |
| **Age Restriction** | • DME, DR w/ DME, AMD, macular edema w/RVO: 18 years and older.<br>• ROP: ≤ 52 weeks chronological age |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist |
| **Coverage Duration** | • AMD, DME, DR w/ DME, & RVO: Limited to a maximum of 13 injections per 12 months (per eye).<br>• ROP: 1 dose per affected eye per request |
| **Other Requirements & Information** | <u>Renewal or retreatment requests:</u><br><u>AMD, DME, DR w/ DME, PDR, & RVO:</u><br>Renewal will be based on documentation of benefit from therapy (may be indicated on the TAR unless clinic notes are specifically requested).<br>Baseline and updated vision status maybe requested with evidence of:<br>1) Improvement or stabilization compared to baseline OR<br>2) Decrease in rate of vision loss compared to baseline |

# Requirements for Intravitreal Aflibercept (Eylea™), Aflibercept-ayyh (Pavblu™), Aflibercept-abzv (Enzeevu™), Aflibercept-mrbb (Ahzantive™), and Alfibercept-yzvy (Opuviz™)

| | |
|---|---|
| | ROP:<br>1) Current gestational age<br>2) Continues to be positive for diagnosis of a, b or c:<br>a. ROP Zone I stage 1+, 2+, 3, & 3+<br>b. ROP Zone II Stage 2+, 3+<br>c. AP-ROP (aggressive posterior ROP)<br>3) Has had ≤ 2 prior treatments with aflibercept<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| Product | HCPCS | Description | Dosing, Units |
|---|---|---|---|
| Eylea™ | J0178 | Injection, aflibercept, 1 mg | AMD (all): 2mg every 4 weeks for 3 doses followed by 2 mg every 8 weeks (may be used monthly)<br><br>DME & DR w/ DME, PDR (J0178, Q5147, Q5150, Q5153)2mg every 4 weeks for 5 doses followed by 2mg every 8 weeks (may be used monthly)<br><br>RVO (J0178, Q5147, Q5150, Q5153): 2mg every 4 weeks<br><br>ROP (J0178 only): 0.4 mg into the affected eye, may repeat after a minimum interval of 10 days. |
| Opuviz™ | Q5153 | Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg | |
| Pavblu™ | Q5147 | Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg | |
| Enzeevu™ | Q5149 | Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg | |
| Ahzantive™ | Q5150 | Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg | |

# Requirements for Faricimab Intravitreal Injection (Vabysmo™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Diabetic macular edema (DME)<br>2) Neovascular (wet) age-related macular degeneration (nAMD)<br>3) Macular edema following retinal vein occlusion (RVO) |
| **Exclusion Criteria** | Members with active ocular or periocular infection |
| **Required Medical Information** | 1) Clinic notes to confirm the diagnosis submitted<br>2) Baseline visual acuity score<br>3) If the eye is previously untreated with a vascular endothelial growth factor (VEGF) inhibitor, documentation of trial and failure to, or reason(s) why preferred VEGF inhibitor, bevacizumab, cannot be used (ophthalmic use of bevacizumab does not require a TAR)<br>4) Documentation of trial and failure or contraindication to at least one of the following (a, b, or c):<br>a. ranibizumab (Lucentis™, or biosimilar)<br>b. aflibercept (Eylea™, or biosimilar)<br>c. brolucizumab-dbll (Beovu™) |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Must be prescribed or recommended by an ophthalmologist |
| **Coverage Duration** | Limited to a maximum of 13 injections per eye in 12 months |
| **Other Requirements** | Renewal authorization will be based on documentation of benefit from therapy (may be indicated on TAR unless clinic notes are specifically requested).<br>Baseline and updated vision status maybe requested with evidence of:<br>1) Improvement or stabilization compared to baseline or<br>2) Decrease in rate of vision loss compared to baseline<br><br>Requests for off-label use: See Partnership criteria document, *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Faricimab Intravitreal Injection (Vabysmo™)

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2777 | Intravitreal injection, faricimab, per 0.1 mg | **nAMD:**<br>• Initial -- 6 mg (60 HCPCS units) every 4 weeks for the first 4 doses (weeks 1-16): Total of 240 units authorized per eye (480 max units for bilateral treatment) for initial TARs.<br>• Continuation – depending on evaluations at 8 & 12 weeks following the initial 4 doses, subsequent doses may be repeated at 4-16 week intervals.<br><br>**DME:**<br>Two regimens are FDA approved:<br>• 6 mg every 4 weeks for at least 4 doses. Following resolution of edema, doses are continued every 4-8 weeks (intervals modified +/- depending on CST & visual acuity evaluations) through week 52 OR<br>• 6 mg every 4 weeks for the first 6 doses, followed by 6 mg every 8 weeks over the next 28 weeks. Some may need every 4 weeks dosing after the first 4 doses.<br><br>**RVO:**<br>• 6 mg every 4 weeks for 6 doses, may be continued at intervals of every 4 weeks or greater for ongoing ME |

# Requirements for Revakinagene Taroretcel-lwey (Encelto™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic macular telangiectasia (MacTel) type 2 |
| **Exclusion Criteria** | • Idiopathic macular telangiectasia type 1<br>• Neovascular macular telangiectasia type 2<br>• Member has evidence of central serous chorio-retinopathy in either eye<br>• Member has a history of ocular herpes virus in either eye |
| **Required Medical Information** | Documentation of the following is required for each eye requesting treatment:<br>1) Diagnosis of MacTel with evidence of fluorescein leakage typical of MacTel and at least one of the other features that include (a, b, c, d, or e):<br>a. hyperpigmentation that is outside of a 500 micron radius from the center of the fovea, or<br>b. retinal opacification, or<br>c. crystalline deposits, or<br>d. right-angle vessels, or<br>e. inner/outer lamellar cavities<br>2) Photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm2 measured by spectral domain-optical coherence tomography (SD-OCT)<br>3) Baseline best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening.<br>4) No evidence of neovascular MacTel type 2<br><br>Policy MCUP3138 External Independent Medical Review will apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals (ie denials for medical necessity) |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Once per eye per lifetime |
| **Other Requirements & Information** | Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Revakinagene Taroretcel-lwey (Encelto™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J3403 | Revakinagene taroretcel-lwey, per implant (Encelto) | One implant per eye per lifetime.<br><br>*Each implant contains 200,000 to 440,000 allogeneic retinal pigment 151 epithelial cells expressing recombinant human ciliary neurotropic factor (rhCNTF)* |

# Requirements for Pegcetacoplan (Syfovre™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) |
| **Exclusion Criteria** | • Choroidal neovascularization (CNV) in either eye<br>• GA is secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies)<br>• Ocular or periocular infection<br>• Active intraocular inflammation |
| **Required Medical Information** | 1) Diagnosis of GA secondary to AMD<br>2) Best corrected visual acuity (BCVA) ≥ 24 ETDRS letters (20/320 Snellen equivalent or better)<br>3) GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2<br>4) Presence of extrafoveal lesions |
| **Age Restriction** | 60 years and older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Initial and renewal: 12 months |
| **Other Requirements & Information** | Renewal criteria: documentation of a positive clinical response to therapy which may include a reduction or stabilization in the rate of vision decline, or stabilization or reduction in total area of GA lesions.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2781 | Injection, pegcetacoplan, intravitreal, 1 mg | 15 mg (0.1 mL) into affected eye(s) once every 25 to 60 days |

# Requirements for Avacincaptad Pegol (Izervay™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) |
| **Exclusion Criteria** | • Choroidal neovascularization (CNV) in either eye<br>• GA is secondary to any conditions other than AMD (for example, Stargardt disease, cone rod dystrophy, toxic maculopathies)<br>• Ocular or periocular infection<br>• Active intraocular inflammation |
| **Required Medical Information** | 1) Diagnosis of GA not affecting the foveal center point, secondary to AMD<br>2) Best corrected visual acuity (BCVA) between 20/25 and 20/320<br>3) GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2 |
| **Age Restriction** | 50 years or older |
| **Prescriber Restriction** | Ophthalmologist |
| **Coverage Duration** | Initial and renewal: 12 months |
| **Other Requirements & Information** | Renewal criteria: documentation of a positive clinical response to therapy which may include a reduction or stabilization in the rate of vision decline, or stabilization or reduction in total area of GA lesions.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2782 | Injection, avacincaptad pegol, 0.1 mg | 2 mg (0.1 mL) into affected eye(s) once monthly (~every 21 to 35 days) |

# Requirements for Romosozumab-aqqg SC Injection (Evenity™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of severe osteoporosis in members who are at high risk for osteoporotic fracture, defined as a history of osteoporotic fracture, or who have multiple risk factors for fracture. |
| **Exclusion Criteria** | • Risk for osteosarcoma (Paget's disease of bone, history of prior radiation therapy, unexplained elevation of alkaline phosphatase, open epiphyses, prior external beam or implant radiation therapy involving the skeleton).<br>• Primary or secondary hyperparathyroidism.<br>• Other hypercalcemic disorders.<br>• Members who have significant cardiovascular risk such as myocardial infarction or stroke in the preceding 12 months. |
| **Required Medical Information** | **All Requests**:<br>1. Clinic notes documenting osteoporotic fracture history and/or fragility fractures.<br>2. BMD T-Score.<br><br>**For High Fracture Risk**:<br>1. Trial and failure (or contraindication) to **both** preferred treatments (bisphosphonate AND denosumab).<br>a. Documentation of treatment failure defined as a decline in T-score of greater than or equal to 5 percent after 2 years of adherent use with a bisphosphonate and/or denosumab (Prolia™) therapy (both if failure to one; just one if there's a contraindication to the other).<br>2. Trial and failure or reasons why teriparatide (Forteo™) and abaloparatide (Tymlos™) cannot be used.<br>3. Documentation of high fracture risk with one of the following:<br>a. History of a prior spine fracture, hip fracture, or fragility fracture; OR<br>b. Femoral neck, total hip, or lumbar spine T-Score ≤ - 2.5; OR<br>c. Femoral neck, total hip, or lumbar spine T-Score between -1 and -2.4, together with a FRAX score ≥ 3% for hip fracture risk or ≥ 20% for major osteoporotic fracture risk.<br><br>**For Very High Fracture Risk:**<br>1. Documentation of very high fracture risk with one of the following:<br>a. Femoral neck, total hip, or lumbar spine T-Score ≤ -2.5, with spine, hip, or fragility fracture<br>b. Femoral neck, total hip, or lumbar spine T-Score ≤ -3.0, regardless of fracture history or status.<br>c. Fractures while on approved osteoporosis therapy<br>d. History of multiple fractures<br>e. Fractures while on drugs that cause skeletal harm (e.g., long-term glucocorticoids)<br>f. Very high probability by FRAX (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) |
| **Age Restriction** | 18 years and older. |
| **Prescriber Restriction** | Prescribed by or recommended by an Endocrinologist or Orthopedist. |
| **Coverage Duration** | 12 months maximum treatment duration per lifetime. |

# Requirements for Romosozumab-aqqg SC Injection (Evenity™)

| | |
|---|---|
| **Other Requirements & Information** | Renewal requests beyond the 12-month lifetime maximum will not be approved.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J3111 | Injection, romosozumab-aqqg, 1 mg | 210mg injected subcutaneously once monthly for a maximum duration of 12 doses. |

# Requirements for Teplizumab-mzwv (Tzield™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Delay onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years an older with Stage 2 T1D. |
| **Exclusion Criteria** | Current diagnosis of Stage 3 T1D |
| **Required Medical Information** | Diagnosis of Stage 2 type 1 diabetes confirmed by all of the following:<br>1) Documentation of at least 2 of the following type 1 diabetes-related autoantibodies within the last 6 months:<br>a. Islet cell autoantibody (ICA)<br>b. Glutamic acid decarboxylase 65 (GAD) autoantibody<br>c. Zinc transporter 8 autoantibody (ZnT8A)<br>d. Insulinoma-associated antigen 2 autoantibody (IA-2A)<br>e. Insulin autoantibody (IAA)<br>2) Documentation of dysglycemia without overt hyperglycemia within the preceding 2 months defined as one of the following (oral glucose tolerance test preferred):<br>a. Fasting plasma glucose level 100-125 mg/dL; OR<br>b. Two-hour postprandial plasma glucose 140-199 mg/dL; OR<br>c. Postprandial glucose level at 30, 60 or 90 minutes ≥ 200 mg/ dL; OR<br>d. A1C 5.7-6.4%<br>3) Documentation type 2 diabetes has been ruled out based on clinical history.<br>4) Body surface area (BSA).<br>5) Administering facility must be able to accommodate 14 consecutive calendar days of administration. |
| **Age Restriction** | 8 years and older |
| **Prescriber Restriction** | Endocrinologist |
| **Coverage Duration** | 14-day treatment course only, once per lifetime. |
| **Other Requirements** | Note, prior to initiating therapy, provider must have awareness of the following:<br>1) Completion of age-appropriate vaccinations.<br>2) No evidence of active serious infections (i.e. Epstein-Barr virus or cytomegalovirus infection).<br>3) Adequate hepatic function at baseline (i.e. ALT/AST, bilirubin)<br>4) Adequate hematologic function at baseline (i.e. platelets, hemoglobin, absolute neutrophil count, lymphocytes).<br>5) Member is not pregnant.<br><br>Note that each 2 ml single dose vial (SDV) contains 2,000 mcg (2 mg), equivalent to 400 HCPCS billing units per vial. Vials are diluted to 100 mcg/ml and must be administered within 4 hours of being diluted, with remainder discarded (see Partnership Drug Waste policy for billing waste with JW modifier.<br><br>TARs must include both the dose and anticipated waste amounts. Waste units must be billed separately from the administered dose units, using the JW modifier as stated in Policy MPRP4062, Drug Wastage Payments. The number of units on the authorized |

# Requirements for Teplizumab-mzwv (Tzield™)

| | |
|---|---|
| | TAR will be sufficient for both dose and waste claims.<br>1 vial per day is sufficient for all doses up to a BSA of 1.94 $m^2$. Requests for more than 1 vial (400 billing units) per day must include the member's current BSA. |

**Medical Billing:**

Dose limits & billing requirements (approved TAR is required):

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J9381 | Injection, teplizumab-mzwv, 5 mcg | Administer once daily for 14 consecutive days. A single vial (2 ml=2,000 mcg) is 400 HCPCS units (5 mcg/unit). For BSA </= 1.94 m2, maximum reimbursement is for 1 vial, 400 units (includes dose + waste).<br>Day 1: 65 mcg/m2 body surface area (BSA)<br>Day 2: 125 mcg/m2 BSA IV once daily<br>Day 3: 250 mcg/m2 BSA<br>Day 4: 500 mcg/m2 BSA<br>Day 5 to day 14: 1,030 mcg/m2 BSA once daily<br><br>If a planned infusion dose is missed, resume dosing by administering all remaining doses on consecutive days to complete the 14-day treatment course. |

# Requirements for mirikizumab-mrkz (Omvoh™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | IV induction dosage for the treatment of moderately to severely active ulcerative colitis (UC) and Crohn's Disease (CD) in adults. |
| **Exclusion Criteria** | • Active, serious infection, latent (untreated) tuberculosis<br>• Combination with another monoclonal antibody/biologic therapy |
| **Required Medical Information** | 1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated).<br>2) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease.<br>3) Treatment plan including dose and schedule of mirikizumab (Omvoh™) requested<br>4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (e.g., Quanti FERON-TB Gold test).<br>5) Baseline liver enzyme and bilirubin levels prior to treatment initiation.<br>6) Documented therapeutic failure to induce remission with (or contraindication to) both of the following (a and b)<br>a. TNF inhibitor (TNFi): adalimumab, infliximab (Inflectra™-preferred PA group 1) (Avsola™, Renflexis™-PA group 2), certolizumab (CD indication only) or subcutaneous golimumab (UC indication only)<br>b. Ustekinumab<br><br>Requests for treating indeterminate colitis (where distinction between CD and UC cannot be made) will be considered on a case-by-case basis. |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Prescribed or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial approval for 3 doses of 300 mg for induction dose. Member will transition to subcutaneous form for self-administration for maintenance per FDA indicated dosage and will need to obtain through MediCal Rx benefit. |
| **Other Requirements & Information** | Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for mirikizumab-mrkz (Omvoh™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2267 | Injection, mirikizumab-mrkz, 1 mg | UC: Induction: IV: 300 mg at weeks 0, 4, and 8. Maintenance: SUBQ dispensed as pharmacy benefit: 200 mg at week 12 and then every 4 weeks.<br><br>CD: Induction: IV: 900 mg at weeks 0, 4, and 8. Maintenance: SUBQ dispensed as pharmacy benefit: 300 mg at week 12 and then every 4 weeks |

# Requirements for Intravenous Risankizumab-rzaa (Skyrizi™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | • Moderate to severe Crohn's disease (CD)<br>• Moderate to severe ulcerative colitis (UC) |
| **Exclusion Criteria** | • Active, serious infection, latent (untreated) tuberculosis<br>• Combination with another monoclonal antibody/biologic therapy |
| **Required Medical Information** | **Crohn's Disease/Ulcerative Colitis:**<br>1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated).<br>2) Treatment plan.<br>3) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test).<br>4) Documented therapeutic failure to induce remission with or contraindication to both of the following (a AND b):<br>a. TNF Inhibitor: adalimumab, infliximab (Inflectra™-preferred PA group 1) (Avsola™, Renflexis™-PA group 2), certolizumab (CD indication only) or subcutaneous golimumab (UC indication only)<br>b. Ustekinumab<br><br>Requests for treating indeterminate colitis (where distinction between CD and UC cannot be made) will be considered on a case-by-case basis.<br><br>Requests for moderate to severe plaque psoriasis and psoriatic arthritis:<br>This medication is typically self-administered by the member or a caregiver at home. See the additional requirements for medical claim TARs in the PHC criteria document titled Standard Requirements for Self-Administered Drugs. |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Prescribed or in consultation with a gastroenterologist |
| **Coverage Duration** | 3 months for induction dose only. Member will transition to subcutaneous form for self-administration for maintenance per FDA indicated dosage and will need to obtain through MediCal Rx benefit. |
| **Other Requirements & Information** | Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Intravenous Risankizumab-rzaa (Skyrizi™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J2327 | Intravenous injection, Risankizumab-rzaa, per dose | CD: Loading Dose (IV): 600 mg on weeks 0, 4 and 8 (Followed by maintenance dose 180 mg to 360 mgSUBQ starting at week 12 and then every 8 weeks thereafter)<br><br>UC: Loading Dose (IV): 1200 mg on weeks 0, 4, and 8 (Followed by maintenance dose 180 to 360 mg SUBQ stating at week 12 and then every 8 weeks thereafter)_ |

# Requirements for IV Ustekinumab (Stelara™) and biosimilars Ustekinumab-auub (Wezlana™), -ttwe (Pyzchiva™), -aekn (Selarsdi™), -aauz (Otulfi™), -srlf (Imuldosa™), -stba (Steqeyma™), -kfce (Yesintek™), (IV products only)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | IV induction dosage (single dose) for the treatment of moderately to severely active Crohn's disease (CD) or ulcerative colitis (UC). |
| **Exclusion Criteria** | • Active, serious infection, latent (untreated) tuberculosis<br>• Combination with another monoclonal antibody/biologic therapy |
| **Required Medical Information** | 1) Specialist's clinic notes documenting disease course with evidence of active disease &/or inflammation as appropriate by diagnosis (imaging, labs, or other findings as indicated).<br>2) Treatment plan (Note: the single induction dose is recommended to be followed by 90 mg subcutaneous dose 8 weeks after induction dose, and every 8 weeks thereafter).<br>3) Disease Activity Score or patient specific symptoms/treatment history to confirm moderately to severely active disease.<br>4) Awareness of immune-suppression risks specific to latent TB infection, and order exists for TST (Tuberculin Skin Test/PPD) or Interferon Gamma Release Assay (eg, Quanti FERON-TB Gold test). |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Prescribed or in consultation with a gastroenterologist |
| **Coverage Duration** | Single fill/date of service. FDA indicated dosing is for a single IV dose for induction, followed by subcutaneous dosing thereafter. |
| **Other Requirements & Information** | Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J3358 | Ustekinumab, for IV injections, 1 mg (only indicated for Crohn's or UC induction) | |
| Q5138 | Injection, ustekinumab-auub (Wezlana), biosimilar, intravenous, 1 mg (only indicated for Crohn's or UC induction) | |
| Q9997 | Injection, ustekinumab-ttwe (Pyzchiva), intravenous, 1 mg (only indicated for Crohn's or UC induction) | |
| Q9998 | Injection, ustekinumab-aekn (Selarsdi), 1 mg (only indicated for Crohn's or UC induction) | |
| Q9999 | Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg | |
| Q5100 | Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg | |
| Q5098 | Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg | |
| Q5099 | Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg | |

| Member Weight | Recommended Dose |
|---|---|
| ≤55 kg | 260 mg IV x 1 |
| 54-85 kg | 390 mg IV x 1 |
| ≥86 kg | 520 mg IV x 1 |

*With transition to subcutaneous dosing after the initial IV induction dose*

# Requirements for Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | 1) Generalized myasthenia gravis (MG) in adults who are anti-acetylcholine receptor (AChR) antibody positive<br>2) Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo only)<br><br>*Vyvgart Hytrulo PFS is a self-administered product and will fall under Partnership's Standard Requirements for Self-Administered Drugs* |
| **Exclusion Criteria** | • Myasthenia gravis MuSK antibody, LRP4 antibody positive or seronegative<br>• Concurrent use with other systemic Complement Inhibitors or Neonatal Fc Receptor Antagonists |
| **Required Medical Information** | <u>Generalized Myasthenia Gravis (MG):</u><br>1) Positive immunologic binding assay to confirm MG due to the presence of AChR antibodies<br>2) Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium<br>3) Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5 with at least 50% of the score coming from non-ocular symptoms at baseline<br>4) Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV<br>5) Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to all of the following:<br>• Pyridostigmine<br>• Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND<br>• Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate<br>• Self-administered efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™)<br><br><u>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo only):</u><br>1) Confirmation of diagnosis based on the European Academy of Neurology (EAN/PNS) guidelines (see Other Requirements and Information for EAN/PNS criteria)<br>2) Electro diagnostic findings of peripheral nerve demyelination<br>3) Exclusion of other similar disease states that overlap with similar symptoms, such as but not limited to:<br>a. Neuropathy probably caused by B. burgdorferi infection (Lyme disease), diphtheria, drug or toxin exposure<br>b. Hereditary demyelinating neuropathy<br>c. Prominent sphincter disturbance<br>d. Diagnosis of multifocal motor neuropathy (MMN)<br>e. IgM monoclonal gammopathy with high titer antibodies to myelinassociated glycoprotein (MAG)<br>f. Other causes for a demyelinating neuropathy including POEMS syndrome, osteosclerotic myeloma, and diabetic and nondiabetic lumbosacral radiculoplexus neuropathy; peripheral nervous system lymphoma and amyloidosis may occasionally have demyelinating |

# Requirements for Efgartigimod alfa-fcab (Vyvgart™) and Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™)

| | |
|---|---|
| | features<br>4) Inflammatory Neuropathy Cause and Treatment (INCAT) score, Inflammatory Rasch-built Overall Disability Scale (I-RODS) or similar measurement of impairment<br>5) Documentation of failure to respond to glucocorticoids (oral or injectable) or reason(s) why glucocorticoids cannot be used such as but not limited to:<br>a. Contraindication<br>b. Severe disability<br>c. Pure motor phenotype<br>d. Fast progressive disease<br>6) Documentation of inadequate response, significant intolerance, or contraindication to intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG)<br>7) Documentation of trial and failure, intolerance or reason(s) why self-administered efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™) cannot be used |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Neurology |
| **Coverage Duration** | MG: Initial: 6 months<br>CIDP: Initial: 3 months<br><br>Renewals (MG & CIDP): 12 months |
| **Other Requirements & Information** | Renewal Requests: MG:<br>• Clinical notes with current: MG-ADL and MGFA classification.<br><br>Renewal Requests: CIDP:<br>• Inflammatory Neuropathy Cause and Treatment (INCAT) score, Inflammatory Rasch-built Overall Disability Scale (I-RODS) or similar measurement of impairment.<br>• If symptoms do not improve or continue to progress after an initial two-to-three-month treatment trial, the patient should be reevaluated to verify the diagnosis of CIDP.<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

| **EAN/PNS 2021 CIDP Guidelines Diagnostic Criteria** | |
|---|---|
| Typical CIDP | 1. Progressive or relapsing, symmetric, proximal and distal muscle weakness of upper and lower limbs, and sensory involvement of at least two limbs<br>2. Developing over at least 8 weeks<br>3. Absent or reduced tendon reflexes in all limbs<br>4. At least two motor nerves must have abnormalities which fulfil the motor conduction criteria. If criteria are fulfilled in only one nerve, the diagnosis is possible typical CIDP. See **Box: Motor Nerve Conduction Criteria** below.<br>5. Sensory conduction abnormalities must be present in at least two nerves. See **Box: Sensory Nerve Conduction Criteria** below.<br><br>Note: In patients suspected of having typical CIDP because they |

| | | |
|---|---|---|
| | | fulfil clinical criteria but not minimal electrodiagnostic criteria, the diagnosis of possible typical CIDP may be made if there is objective improvement following treatment with IVIg, corticosteroids or plasma exchange AND if at least one additional supportive criterion (2-5) is fulfilled. See **Box: Supportive Criterion** below. |
| | Distal CIDP | 1. Progressive or relapsing, symmetric, distal sensory loss and muscle weakness predominantly in lower limbs<br>2. Developing over at least 8 weeks<br>3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs).<br>6. Motor conduction criteria fulfilment is required in at least two upper limb nerves to confirm the clinical diagnosis of distal CIDP. The distal negative peak CMAP amplitude should be at least 1 mV. When criteria are fulfilled in two lower limb but not upper limb nerves or if criteria are fulfilled in only one upper limb nerve, the maximum diagnostic certainty is possible distal CIDP. See **Box: Motor Nerve Conduction Criteria** below.<br>4. Sensory conduction abnormalities must be present in at least two nerves. See **Box: Sensory Nerve Conduction Criteria** below. |
| | Multifocal CIDP | 1. Progressive or relapsing, sensory loss and muscle weakness in a multifocal pattern, usually asymmetric, upper limb predominant, in more than one limb<br>2. Developing over at least 8 weeks<br>3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs).<br>7. Motor conduction criteria fulfilment is required in at least two nerves in total in more than one limb. When criteria are fulfilled in only one nerve, the maximum diagnostic certainty is possible multifocal CIDP. See **Box: Motor Nerve Conduction Criteria** below.<br>4. Sensory conduction abnormalities must be present in at least two nerves of the affected limbs for the diagnosis of multifocal CIDP. See **Box: Sensory Nerve Conduction Criteria** below. |
| | Focal CIDP | 1. Progressive or relapsing, sensory loss and muscle weakness in only one limb.<br>2. Developing over at least 8 weeks.<br>3. Absent or reduced tendon reflexes in affected limbs (tendon reflexes may be normal in unaffected limbs).<br>8. Motor conduction criteria fulfilment is required in at least two nerves in total in more than one limb to confirm the clinical diagnosis of multifocal CIDP and in at least two nerves in one limb for the diagnosis of focal CIDP. When criteria are fulfilled in only one nerve, the maximum diagnostic certainty is possible multifocal or possible focal CIDP. See **Box: Motor Nerve Conduction Criteria** below.<br>4. Sensory conduction abnormalities must be present in at least two nerves of the affected limb for the diagnosis of focal CIDP and in one nerve of the affected limb for the diagnosis of possible focal CIDP. See **Box: Sensory Nerve** |

| | |
|---|---|
| | **Conduction Criteria** below. |
| Motor CIDP (and motor-predominant) | 1. Progressive or relapsing, symmetric, proximal and distal muscle weakness of upper and lower limbs, without sensory involvement.<br>2. Developing over at least 8 weeks<br>3. Absent or reduced tendon reflexes in all limbs<br>9. Motor CIDP must fulfil motor conduction criteria in at least two nerves and sensory conduction must be normal in all of at least four nerves (median, ulnar, radial, and sural) to confirm the clinical diagnosis of motor CIDP. If criteria are fulfilled in only one motor nerve, the diagnosis is possible motor CIDP. See **Box: Motor Nerve Conduction Criteria** below.<br><br>Note: Motor CIDP with sensory conduction abnormalities in two nerves is diagnosed as motor-predominant CIDP. |
| Sensory CIDP (and sensory predominant) | 1. Progressive or relapsing, symmetric sensory involvement of at least two limbs, without motor involvement.<br>2. Developing over at least 8 weeks<br>3. Absent or reduced tendon reflexes in all limbs<br>4. Sensory CIDP must fulfil sensory conduction criteria and motor conduction must be normal in all of at least four nerves (median, ulnar, peroneal, and tibial) to confirm the clinical diagnosis. The maximum diagnostic certainty is possible sensory CIDP. See **Box: Sensory Nerve Conduction Criteria** below.<br><br>Note: Sensory CIDP with motor conduction criteria fulfilled in one nerve is diagnosed as possible sensory-predominant CIDP. If motor conduction criteria are fulfilled in two nerves, the diagnostic certainty increases to sensory-predominant CIDP. |
| Motor Nerve Conduction Criteria: | One of the following strongly supports demyelination (if the criteria only applies to 1 nerve, it is weakly supportive):<br>1. Motor distal latency prolongation ≥50% above ULN in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome), or<br>2. Reduction of motor conduction velocity ≥30% below LLN in two nerves, or<br>3. Prolongation of F-wave latency ≥20% above ULN in two nerves (≥50% if amplitude of distal negative peak CMAP <80% of LLN), or<br>4. Absence of F-waves in two nerves (if these nerves have distal negative peak CMAP amplitudes ≥20% of LLN) + ≥1 other demyelinating parametera in ≥1 other nerve, or<br>5. Motor conduction block: ≥30% reduction of the proximal relative to distal negative peak CMAP amplitude, excluding the tibial nerve, and distal negative peak CMAP amplitude ≥20% of LLN in two nerves; or in one nerve + ≥ 1 other demyelinating parametera except absence of F-waves in ≥1 other nerve, or<br>6. Abnormal temporal dispersion: >30% duration increase between the proximal and distal negative peak CMAP (at least 100% in the tibial nerve) in ≥2 nerves, or |

| | | |
|---|---|---|
| | | 7. Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) prolongation in ≥1 nerveb + ≥1 other demyelinating parametera in ≥1 other nerve<br>a. (LFF 2 Hz) median > 8.4 ms, ulnar > 9.6 ms, peroneal > 8.8 ms, tibial > 9.2 ms<br>b. (LFF 5 Hz) median > 8.0 ms, ulnar > 8.6 ms, peroneal > 8.5 ms, tibial > 8.3 ms<br>c. (LFF 10 Hz) median > 7.8 ms, ulnar > 8.5 ms, peroneal > 8.3 ms, tibial > 8.2 ms<br>d. (LFF 20 Hz) median > 7.4 ms, ulnar > 7.8 ms, peroneal > 8.1 ms, tibial > 8.0 ms |
| | Sensory Nerve Conduction Criteria | 1. For a diagnosis of CIPD: Sensory conduction abnormalities (prolonged distal latency, or reduced SNAP amplitude, or slowed conduction velocity outside of normal limits) in two nerves.<br>2. For a diagnosis of "possible CIPD":<br>a. sensory nerve conduction velocity <80% of LLN (for SNAP amplitude >80% of LLN) or <70% of LLN (for SNAP amplitude <80% of LLN) in at least two nerves (median, ulnar, radial, sural nerve), OR<br>b. Sural sparing pattern (abnormal median or radial sensory nerve action potential [SNAP amplitude] with normal sural nerve SNAP amplitude) (excluding carpal tunnel syndrome). |
| | Supportive Criterion | 1. Objective response to treatment with immunomodulatory agents (IVIg, plasma exchange, corticosteroids). The changes required to define improvement have not been adequately validated. The following which have been used in clinical trials can serve as a guide:<br>a. I-RODS: + ≥4 centile points<br>b. INCAT disability scale: − ≥1 point<br>c. mISS: − ≥2 points<br>d. MRC sum score (0-60): + ≥2 to 4 points*<br>e. Grip strength: Martin Vigorimeter: + ≥8 to 14 kPa* OR Jamar hand grip dynamometer: + ≥10%**<br>2. Imaging: only recommended when diagnosis is "possible CIDP": before concluding that ultrasound or MRI abnormalities are supportive of CIDP, there should be no laboratory/clinical features that suggest other diseases that mimic CIDP (these are listed).<br>a. Ultrasound showing nerve enlargement of at least two sites in proximal median nerve segments and/or the brachial plexus<br>b. MRI showing enlargement and/or increased signal intensity of nerve root(s) on T2 weighted MRI sequences (DIXON/STIR, coronal + sagittal planes)<br>3. CSF evaluation: only recommended when diagnosis is "possible CIDP": sensitivity of CSF protein elevation for CIDP was 68% using cut-offs of ≥0.5 g/L under the age of 50 years and >0.6 g/L over the age of 60 years. |

| | | | |
|---|---|---|---|
| | | 4. Nerve Biopsy: only recommended when CIDP is suspected but cannot be confirmed with other tests. Factors probably supporting the diagnosis of CIDP may be:<br>a. thinly myelinated axons and small onion bulbs.<br>b. thinly myelinated or demyelinated internodes in teased fibers.<br>c. perivascular macrophage clusters.<br>d. supportive features of demyelination on electron microscopy | |

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| Product | HCPCS | Description | Dosing, Units |
|---|---|---|---|
| Vyvgart | J9332 | Injection, efgartigimod alfa-fcab, 2 mg | 10 mg/kg IV once weekly for 4 weeks. Subsequent cycles are repeated at least 50 days from the start of the previous cycle.<br><br>Members weighing more than 120 kg: Maximum dose is 1.2 g IV. |
| Vyvgart Hytrulo | J9334 | Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc | MG:<br>1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase once weekly for 4 weeks. Subsequent cycles are repeated at least 50 days from the start of the previous cycle.<br><br>CIDP:<br>1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase once weekly |

*Vyvgart Hytrulo PFS is a self-administered product and will fall under Partnership's Standard Requirements for Self-Administered Drugs*

# Requirements for Intravenous Nipocalimab-aahu (Imaavy™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized myasthenia gravis (MG) in patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive. |
| **Exclusion Criteria** | • Myasthenia gravis LRP4 antibody positive or seronegative<br>• Concurrent use with other systemic Complement Inhibitors or Neonatal Fc Receptor Antagonists |
| **Required Medical Information** | 1) Positive immunologic binding assay to confirm MG due to the presence of AChR or MuSK antibodies<br>2) Avoidance of drugs that may exacerbate MG if possible, such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium<br>3) Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline<br>4) Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV<br>5) Current weight<br>6) Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to ALL of the following:<br>• Pyridostigmine AND<br>• Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND<br>• Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate, AND<br>• For anti-AChR antibody positive only: Efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™) (preferred) or Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo™). |
| **Age Restriction** | 12 years and older |
| **Prescriber Restriction** | Neurology |
| **Coverage Duration** | Initial: 6 months<br>Renewal: 12 months |
| **Other Requirements & Information** | Renewal Requests:<br>• Clinical notes with current:<br>  ○ MG-ADL<br>  ○ MGFA classification<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Intravenous Nipocalimab-aahu (Imaavy™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| C9305 | Injection, nipocalimab-aahu, 3 mg (Imaavy) | 30mg/kg as a single dose, followed 2 weeks later by 15mg/kg given every 2 weeks thereafter. |

# Requirements for Rozanolixizumab-noli (Rystiggo™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized myasthenia gravis (MG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive. |
| **Exclusion Criteria** | • Myasthenia gravis LRP4 antibody positive or seronegative<br>• Concurrent use with other systemic Complement Inhibitors or Neonatal Fc Receptor Antagonists |
| **Required Medical Information** | 1) Positive immunologic binding assay to confirm MG due to the presence of AChR or MuSK antibodies<br>2) Avoidance of drugs that may exacerbate MG if possible such as but not limited to: Beta blockers, hydroxychloroquine, gabapentin, lithium<br>3) Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥ 6 at baseline<br>4) Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV<br>5) Documentation to indicated trial and failure (insufficient response) or reason(s) for contraindication to ALL of the following:<br>• Pyridostigmine AND<br>• Moderate to high dose glucocorticoids (onset 2-3 weeks and peaks 5.5 months), tapered to the lowest effective dose AND<br>• Oral glucocorticoid sparing immunomodulator, such as: azathioprine, cyclosporine, tacrolimus or mycophenolate, AND<br>• For anti-AChR antibody positive only: Efgartigimod alfa and hyaluronidase-qvfc PFS (Vyvgart Hytrulo PFS™) (preferred), or Efgartigimod alfa-fcab (Vyvgart™) or efgartigimod alfa, 2 mg and hyaluronidase-qvfc (Vyvgart Hytrulo™). |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | Neurology |
| **Coverage Duration** | Initial: 6 months<br>Renewal: 12 months |
| **Other Requirements & Information** | Renewal Requests:<br>• Clinical notes with current:<br>○ MG-ADL<br>○ MGFA classification<br><br>Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Rozanolixizumab-noli (Rystiggo™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J9333 | Injection, rozanolixizumab-noli, 1 mg | Weight based dosing:<br>• Less than 50kg: 420mg<br>• 50kg to less than 100kg: 560mg<br>• 100kg and above: 850mg<br><br>Dose given by subcutaneous infusion once weekly for 6 weeks. Subsequent cycles are repeated at least 63 days from the start of the previous cycle. |

# Requirements for Remestemcel-L-rknd (Ryoncil™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | The treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients |
| **Exclusion Criteria** | • Age ≥18 years<br>• Skin only grade B aGVHD |
| **Required Medical Information** | 1) Diagnosis of grade B–D aGVHD with symptoms involving skin, liver, and/or GI tract (excluding skin-only grade B aGVHD)<br>a. See definition of grading in the Other Requirements & Information section.<br>b. For cases for aGVHD outside of the classical presentation (such as occurring >100 days post-transplant, or presenting with symptoms usually associated with chronic GVHD) histologic confirmation of diagnosis is required.<br>2) Steroid refractory disease defined as progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent).<br>3) Documentation that the GVHD prophylactic regimen has been optimized, such as achieving adequate trough concentrations of calcineurin inhibitors (200-300ng/ml for cyclosporine, or 15ng/ml for tacrolimus), or reasons why these levels cannot be achieved.<br>4) Documentation of trial and failure or reasons why Ruxolitinib (Jakafi™) cannot be used (in members ≥12 years old only).<br><br>Policy MCUP3138 External Independent Medical Review may apply, enabling Partnership to obtain a specialist's evaluation of the case prior to both denials and approvals (ie denials for medical necessity). |
| **Age Restriction** | 2 months to 17 years only |
| **Prescriber Restriction** | Oncologist, hematologist, BMT specialist, or other qualified prescriber |
| **Coverage Duration** | Initial or subsequent flare following complete response: 4 weeks (8 doses)<br>Renewal for partial or mixed response: 4 weeks (4 doses) |
| **Other Requirements & Information** | Renewal requirements:<br>• Requests for continuation following a partial or mixed response:<br>o Documentation of partial response (organ improvement of ≥1 stage without worsening of any other organ) or mixed response (improvement in ≥1 evaluable organ stage with worsening in another) following an initial 4-week course of 8 doses.<br>• Requests for re-treatment following a complete response:<br>o Documentation showing complete response defined as resolution of aGVHD in all involved organs following the initial 4-week course of Ryoncil.<br>o Current aGVHD flare (grade B–D progression after achieving complete response) |

# Requirements for Remestemcel-L-rknd (Ryoncil™)

Definition of International Bone Marrow Transplant Registry Severity Index grades A - D:

| Organ | Stage | Description |
|---|---|---|
| Skin | 1 | Maculopapular rash over <25% of body area |
| | 2 | Maculopapular rash over 25-50% of body area |
| | 3 | Generalized erythroderma |
| | 4 | Generalized erythroderma with bullous formation and often with desquamation |
| Liver | 1 | Bilirubin 2.0-3.0 mg/dL |
| | 2 | Bilirubin 3.1-6.0 mg/dL |
| | 3 | Bilirubin 6.1-15.0 mg/dL |
| | 4 | Bilirubin >15.0 mg/dL |
| Gut | 1 | Diarrhea >30ml/kg or >500ml/day |
| | 2 | Diarrhea >60ml/kg or >1000ml/day |
| | 3 | Diarrhea >90ml/kg or >1500ml/day |
| | 4 | Diarrhea >90ml/kg or >2000ml/day; or severe abdominal pain with or without ileus |
| **International Bone Marrow Transplant Registry Severity Index** | | |
| A – stage 1 skin involvement; no liver or gut involvement | | |
| B – stage 2 skin involvement; stage 1 to 2 gut or liver involvement | | |
| C – stage 3 skin, liver, or gut involvement | | |
| D – stage 4 skin, liver, or gut involvement | | |

Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J3402 | Injection, remestemcel-l-rknd, per therapeutic dose (Ryoncil) | Initial: IV: 2 × $10^6$ mesenchymal stromal cells (MSC)/kg/dose twice weekly for 4 consecutive weeks (total of 8 infusions). Doses should be separated by at least 3 days. Assess clinical response after 28 ± 2 days<br><br>Retreatment: May consider retreatment after 28 days if: Partial or mixed response or GVHD recurs after complete response;<br>• *Partial or mixed response:* IV: 2 × $10^6$ mesenchymal stromal cells (MSC)/**kg**/dose once weekly for 4 additional weeks (total of 4 infusion).<br>• *Recurrence of GVHD after complete remission*: IV: 2 × $10^6$ mesenchymal stromal cells (MSC)/**kg**/dose twice weekly for 4 consecutive weeks (total of 8 infusions). Doses should be separated by at least 3 days.<br>• *No response*: Consider alternative therapy. |

# Requirements for Intravenous Axatilimab (Niktimvo™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy. |
| **Exclusion Criteria** | • Weight ≤40kg |
| **Required Medical Information** | 1) Documentation of the diagnosis of cGVHD including all clinical, laboratory and histologic work up necessary to confirm the diagnosis based on the National Institutes of Health 2014 Consensus Guideline for Diagnosis and Staging (see reference table under Other Requirements & Information).<br>a. For members who lack any of the NIH **Diagnostic** Features, biopsy, organ specific laboratory studies, or evaluation by appropriate specialist may be required to confirm the diagnosis.<br>2) Documentation that the GVHD prophylactic regimen has been optimized, such as achieving adequate trough concentrations of calcineurin inhibitors, or reasons why these levels cannot be achieved.<br>3) Symptoms of cGVHD despite treatment with adequate doses of systemic glucocorticoids AND at least one additional line of systemic therapy, which may include any of the following:<br>a. Ruxolitinib (Jakafi™)<br>b. Ibrutinib (Imbruvica™)<br>c. Belumosudil (Rezurock™)<br>d. Extracorporeal photopheresis<br>e. Mycophenolate mofetil<br>f. Sirolimus<br>g. Rituximab (Rituxan™)<br>h. Bortezomib (Adcetris™)<br>i. Etanercept (Enbrel™)<br>4) Current weight for dosing; member must weigh at least 40kg |
| **Age Restriction** | None |
| **Prescriber Restriction** | Oncologist, hematologist, BMT specialist, or other qualified prescriber |
| **Coverage Duration** | Initial: 6 months<br>Renewal: 12 months |
| **Other Requirements & Information** | Renewal requirements:<br>• Documentation of symptomatic response based on the 2014 NIH Consensus Criteria.<br><br>Diagnostic and distinctive clinical manifestations of chronic graft-versus-host disease based on the National Institutes of Health 2014 Consensus Guideline: |

| Organ/ site | Diagnostic (sufficient to establish the diagnosis of cGHVD) | Distinctive (seen in cGVHD, but insufficient alone to establish diagnosis) |
|---|---|---|
| Skin | • Poikiloderma | • Depigmentation |

# Requirements for Intravenous Axatilimab (Niktimvo™)

| | | |
|---|---|---|
| | • Lichen planus-like features<br>• Sclerotic features<br>• Morphea-like features<br>• Lichen sclerosus-like features | • Papulosquamous lesions |
| Nails | | • Dystrophy<br>• Longitudinal ridging, splitting, or brittle features<br>• Onycholysis<br>• Pterygium unguis<br>• Nail loss (usually symmetric and affects most nails) |
| Scalp and body hair | | • New onset of scarring or nonscarring scalp alopecia (not associated with recovery from chemotherapy or radiotherapy)<br>• Loss of body hair<br>• Scaling |
| Mouth | • Lichen planus-type changes | • Xerostomia<br>• Mucocele<br>• Mucosal atrophy<br>• Pseudomembranes<br>• Ulcers |
| Eyes | | • New-onset dry, gritty, or painful eyes<br>• Cicatricial conjunctivitis<br>• Keratoconjunctivitis sicca<br>• Confluent areas of punctate keratopathy |
| Genitalia | • Lichen planus-like features<br>• Lichen sclerosus-like features<br>• Females: Vaginal scarring or clitoral/labial agglutination<br>• Males: Phimosis or urethral/meatus scarring or stenosis | • Erosions<br>• Fissures<br>• Ulcers |
| GI tract | • Esophageal web<br>• Strictures or stenosis in the upper to mid third of the esophagus | |
| Lung | • Bronchiolitis obliterans diagnosed with lung biopsy | • Bronchiolitis obliterans syndrome (BOS) diagnosed with PFTs and imaging |
| Muscle, fascia, joints | • Fasciitis<br>• Joint stiffness or contractures secondary to fasciitis or sclerosis | • Myositis or polymyositis |

Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

# Requirements for Intravenous Axatilimab (Niktimvo™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J9038 | Injection, axatilimab-csfr, 0.1 mg | 0.3 mg/kg, up to a maximum dose of 35 mg, as an intravenous infusion over 30 minutes every 2 weeks until progression or unacceptable toxicity |

*Note that in clinical trials, higher doses of 1mg/kg and 3mg/kg were studied but were associated with lower overall response rates (worse efficacy) than the 0.3mg/kg dosing.*

# Requirements for Inebilizumab-cdon (Uplizna™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | • Neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) IgG antibody positive.<br>• Immunoglobulin G4-related disease (IgG4-RD) |
| **Exclusion Criteria** | • History of a life-threatening infusion reaction to inebilizumab; active hepatitis B infection; tuberculosis (TB) disease (active TB) or untreated TB infection (latent TB).<br>• NMOSD: Use along with IV eculizumab (Soliris™} or SUBQ satralizumab (Enspryng™)<br>• NMOSD negative AQP4-IgG<br>• IgG4-RD: Use along with rituximab |
| **Required Medical Information** | All requests should include documentation that member has been screened for hepatitis B virus (HBsAg and anti-HBc measurements) and active tuberculosis prior to treatment initiation.<br><br>Submit the following per indication:<br><u>Requests for neuromyelitis optica spectrum disorder (NMOSD) (AQP4 IgG positive) required documentation of ALL of the following:</u><br>1) At least one of the following:<br>• Optic neuritis<br>• Acute myelitis<br>• Area postrema syndrome: Episode of otherwise unexplained hiccups or nausea and vomiting<br>• Acute brainstem syndrome (acute inflammatory demyelination of the primary medulla)<br>• Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions<br>• Symptomatic cerebral syndrome with NMOSD-typical brain lesions<br>2) Seropositive for AQP4-IgG antibodies<br>3) Baseline Expanded Disability Status Scale (EDSS) score<br>4) Provider to submit reason(s) why satralizumab (Enspryng™) cannot be used, as the lower- level of care agent.<br><br><u>Requests for Immunoglobulin G4-related disease (IgG4-RD) require documentation of ALL the following:</u><br>1) Diagnosis of IgG4-RD including documentation to show BOTH of the following:<br>a) Clinical or radiologic evidence of tumor-like swelling of organs involved.<br>b) Biopsy of the involved organs that demonstrates ALL of the following:<br>i) Lymphoplasmacytic infiltrate enriched in IgG4-positive plasma cells<br>ii) Storiform fibrosis (typified by a cartwheel appearance of the arranged fibroblasts and inflammatory cells)<br>iii) Obliterative phlebitis |

# Requirements for Inebilizumab-cdon (Uplizna™)

| | |
|---|---|
| | 2) Other conditions (eg. malignancy, infection, other autoimmune disorders etc) have been ruled out.<br>3) IgG4-RD affecting 2 or more of the following organ/sites at any time:<br>• Pancreas<br>• Bile ducts/biliary tree<br>• Orbits<br>• Lungs<br>• Kidneys<br>• Lacrimal glands<br>• Major salivary glands<br>• Retropertioneum<br>• Aorta<br>• Pachymeninges<br>• Thyroids glands<br>4) Member is experiencing (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoid treatment and/or recurrent disease.<br>a. Flare is defined as new or worsening clinical features of IgG4-RD for which no clear alternative diagnosis exists.<br>5) Refractory to or unable to use glucocorticoids (including glucocorticoid dependence).<br>a. Refractory to glucocorticoids is defined as inability to experience symptom relief, reduction in mass/organ size, improvement in organ function, or adequate decreases in serum IgG4 concentrations from glucocorticoids alone.<br>b. This includes patients who are glucocorticoid-dependent (i.e. unable to reduce glucocorticoid dose to <5 mg/day) without causing disease flare or worsening of symptoms.<br>6) Trial and failure, or contraindication to, rituximab (biosimilar preferred).or explanation from the provider as to why rituximab is not appropriate. |
| **Age Restriction** | 18 years and older |
| **Prescriber Restriction** | NMOSD: Specialty providers may include neurologist, ophthalmologist, immunologist, hematologist or other physician with experience treating NMOSD.<br><br>IgG4-RD: Specialty providers may include rheumatologists, immunologists, endocrinologists, nephrologists, hepatologists, or other physician with experience in treating IgG4-RD. |
| **Coverage Duration** | Initial request with loading dose: 6 months<br><br>Renewal: 12 months with documentation to indicate a positive response to treatment. |
| **Other Requirements & Information** | Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.* |

# Requirements for Inebilizumab-cdon (Uplizna™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units |
|---|---|---|
| J1823 | Intravenous injection, Inebilizumab-cdon, 1 mg | Loading Dose:<br>IV: 300 mg on day 1, followed by 300 mg 2 weeks later on day 15.<br><br>Maintenance Dose:<br>IV: 300 mg every 6 months (6 months starts after the first 300 mg dose) |

# Requirements for Esketamine Nasal Spray (Spravato™)

*Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment-resistant depression (TRD) |
| **Exclusion Criteria** | • Requests for use exceeding the FDA/manufacturer labeled maximum dose.<br>• Failure of the prescriber to provide documentation specified under required medical information indicating an adequate work up of the member was completed.<br>• Any requests in which the medication will be provided directly to the patient for administration outside of a REMS authorized facility.<br>• Active aneurysmal vascular disease or intracerebral hemorrhage or history of intracerebral hemorrhage.<br>• Currently taking a monoamine oxidase inhibiting (MAOI) medication (e.g., isocarboxazid, selegiline).<br>• Active psychosis.<br>• Delirium (within one week of administration).<br>• Hypersensitivity to ketamine or esketamine<br>• Dementia.<br>• Class IV heart failure.<br><br>While not an absolute exclusion, due to the risk of hypertensive crisis, care should be exercised when considering esketamine treatment in individuals currently taking psychostimulant medications, including modafinil and armodafinil. |
| **Required Medical Information** | All participants in esketamine therapy fulfillment must be enrolled in the Spravato REMS program: The facility drug administration site, the member AND the dispensing pharmacy. All providers must have the infrastructure in place to obtain the medication, store the medication, and administer the medication in accordance with REMS guidelines<br><br><u>New Starts require each of the following:</u><br>1) Documentation of current and prior depressive episodes with their duration and all prior treatments including any prior electroconvulsive (ECT) or Transcranial Magnetic Stimulation (TMS) with the date and outcome (note that ECT or TMS is not a requirement for Spravato eligibility).<br>2) Documentation of physical examination and laboratory assessment to rule out other causes of treatment resistant depression including, but not limited to comprehensive metabolic panel (CMP), complete blood count (CBC) and thyroid stimulating hormone (TSH)<br>3) Baseline (prior to Spravato) standardized depression symptom assessment tool results such as one of the following:<br>a. Beck Depression Inventory (BDI)<br>b. Hamilton Depression Rating Scale (HAM-D)<br>c. Inventory of Depressive Symptomatology-Systems Review (IDS-SR)<br>d. Montgomery-Asberg Depression Rating Scale (MADRS)<br>e. Personal Health Questionnaire Depression Scale (PHQ-9)<br>f. Quick Inventory of Depressive Symptomatology (QIDS)<br>4) Documentation of failure to remission after an adequate trial of 2 antidepressants from different medication classes at therapeutic doses during the current depressive episode. |

# Requirements for Esketamine Nasal Spray (Spravato™)

| | |
|---|---|
| | a. Applicable anti-depressant classes for this requirement include SSRIs, SNRIs, Bupropion, Mirtazapine, TCAs, MAOIs, Vilazodone or Vortioxetine. Electroconvulsive (ECT) or Transcranial Magnetic Stimulation (TMS) may also be used as one line of prior therapy.<br>b. If the above antidepressant medications were used concurrently, or with other augmenting agents (i.e., lithium, thyroid hormone, buspirone, second generation antipsychotic) then the regimen taken together for a period of time constitutes one trial.<br>c. The current episode is considered the continuous time that the patient has been symptomatic and meeting clinical diagnostic criteria for MDD, inclusive of present day. Episodes that are separated by periods of symptom remission such that patients no longer meet clinical diagnostic criteria for MDD during that time represent distinct and separate episodes.<br>d. Prescriber will attest that the medication trial was adequate to determine treatment failure or intolerance.<br>5) Pharmacy claim history (or comparable documentation of pharmacy dispensing) must show adherence to both previous and current oral antidepressant regimens. In the absence of pharmacy claim history providers should provide medication name and response to the trial.<br>6) Prescriber attestation that they have evaluated for the presence of current and/or past substance misuse/use disorder and that, if present, clinical risks of treatment with esketamine are outweighed by the potential benefits. In other words, the prescriber has conducted a thorough substance use history (and where history of prior substance misuse or use disorder is ascertained then comprehensive risk/benefit analysis is documented) in addition to attestation that the provider has communicated with the patient about the misuse potential of this medication.<br>7) Urine (or other body fluid) toxicology (UTOX) screening.<br>8) Esketamine (Spravato™) treatment plan.<br>9) Pregnancy test, and for patients who are pregnant or breastfeeding, documentation of comprehensive risk/benefit discussion including contraceptive counseling to those who may become pregnant during treatment.<br>10) Documentation of appropriate CURES query.<br><br><u>Renewals:</u><br>1) Response to therapy assessed with the same standardized rating scale that was provided for the baseline assessment (see above scales listed under requirement 3).<br>2) Urine toxicology with each renewal. |
| **Age Restriction** | Age 18 years and up |
| **Prescriber Restriction** | Board certified psychiatrist is preferred, requests from other prescribers will be reviewed on a case-by-case basis.<br><br>*Providers other than board certified psychiatrists should indicate any formal psychiatric training they have completed on the request.* |
| **Coverage Duration** | Initial approval: 8 weeks (672 – 980 units)<br>Renewal (starting at 9th week of treatment): 26 weeks (728 – 2184 units) |
| **Other Requirements & Information** | Notes:<br>1) TAR review will be by CMO or delegate, since treatment of severe disease is generally under the scope of State Medi-Cal fee for service.<br>2) Partnership is aware that Spravato™ is now also FDA approved for Major |

# Requirements for Esketamine Nasal Spray (Spravato™)

Depressive Disorder with acute suicidal ideation. Members experiencing acute suicidal ideation and at risk of acting upon that ideation should be under clinical (psychiatric or medical) observation. Treatment for serious mental health issues is provided by the county mental health plans. The manufacturer's clinical trials for FDA approval did not show a statistically significant decrease in suicidality scores with esketamine vs placebo; note that suicidality decreased in both the treatment and placebo arms and the study was conducted in an inpatient psychiatric facility. The clinical trials excluded individuals with borderline personality disorder (suicidality is a hallmark of BPD).

3) Regarding cannabis or alcohol use: Although legal CNS depressants, use of either agent, and especially if positive for both, does necessitate a certain level of clinical concern for the potential risk of substance use disorder (SUD).
4) If member declares substance use, or UTOX is positive, TAR requests must have the prescriber documentation as to why this is not a concern or contraindication to administration of esketamine and how benefits outweigh the risks.
5) Regarding members being treated via telemedicine: Telemedicine prescribers are not necessarily exempt from providing esketamine to members as long as all criteria requirements can be incorporated, including Urine Toxicology lab report and administration of esketamine in a REMS enrolled facility with the requisite monitoring post-treatment.
6) Careful review of an individual's current medication list and monitoring of potential drug-drug interactions is standard of care.
7)

Requests for off-label use: See Partnership criteria document *Case-by-Case TAR Requirements and Considerations.*

# Requirements for Esketamine Nasal Spray (Spravato™)

**Medical Billing:**

Dose limits & billing requirements, with an approved TAR:

| HCPCS | Description | Dosing, Units | | |
|---|---|---|---|---|
| S0013 | Esketamine, nasal spray, 1 mg | Individualized to the least frequent dosing needed to maintain remission/response | | |
| | | **FDA Approved Regimens** | **S0013 units per week** | **S0013 units per 4 weeks** |
| | *Initial TAR period* | **Induction phase options (weeks 1-4)** | | |
| | | 56 mg twice a week | 112 | 448 |
| | | *Week 1:* 56mg on day 1, followed by 84mg 3-4 days later<br>*Weeks 2-4*: 84mg twice weekly | Wk 1: 140<br>Wks 2-3: 168 | 644 |
| | | **Maintenance, phase 1 options (weeks 5-8)** | | |
| | | 56mg once weekly | 56 | 224 |
| | | 84mg once weekly | 84 | 336 |
| | | **Maintenance, phase 2 options (weeks 9 & thereafter)** | | |
| | | 56mg every other week | 28 *(average of 56 every other week)* | 112 |
| | | 56mg once weekly | 56 | 224 |
| | | 84mg every other week | 56 *(average of 84 every other week)* | 224 |
| | | 84mg once weekly | 84 | 336 |