Avsola® (infliximab-axxq)
Inflectra ® (infliximab-dyyb)
Infliximab
Remicade ® (inflixima)
Renflexis ® (infliximab-adba)
Effective 11/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		

Contact Information			
	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

FDA approved indications:

Ankylosing Spondylitis: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®
Crohn's Disease, Moderate-to-severe: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®
Crohn's Disease (including fistulizing disease), Moderate-to-severe: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®
Plaque Psoriasis, Moderate-to-severe: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®
Psoriatic Arthritis: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®,
Rheumatoid Arthritis (RA), Moderate-to-severe: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®
Ulcerative colitis, Moderate-to-Severe: Avsola®, Inflectra®, infliximab, Remicade®, Renflexis®,

No PA	PA required
	Avsola® (infliximab-axxq)
	Inflectra® (infliximab-dyyb)
	Infliximab, unbranded
	Remicade® (infliximab)
	Renflexis® (infliximab-abda)

Coverage Guidelines

Authorizations requests will be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Moderate-to-Severe Rheumatoid Arthritis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member meets **ONE** of the following:
    a. Paid claim or provider attestation of inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs
    b. Paid claim or provider attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing†
4. Provider provides clinical rationale for use of the requested agent instead of Enbrel® and Humira®
5. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
6. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Psoriatic arthritis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing†
3. Provider provides clinical rationale for use of the requested agent instead of Enbrel® and Humira®
4. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
5. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Ankylosing Spondylitis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** or contraindication to **ALL** NSAIDs
3. Appropriate dosing†
4. Provider provides clinical rationale for use of the requested agent instead of Enbrel® and Humira®
5. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)

6. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Moderate-to-Severe Plaque Psoriasis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member meets **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** conventional therapies: (see appendix)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing†
4. Provider provides clinical rationale for use of the requested agent instead of Enbrel® and Humira®
5. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
6. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Moderate-to-Severe Crohn's Disease

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dosing†
3. Provider provides clinical rationale for use of the requested agent instead of Humira®
4. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
5. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Fistulizing Crohn's Disease

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dosing †
3. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
4. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Moderate-to-Severe Ulcerative Colitis

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Appropriate dosing†
3. Provider provides clinical rationale for use of the requested agent instead of Humira®
4. If the request is for Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
5. If the request is for BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

† Requests for more frequent or higher doses - see Appendix

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial authorizations will be granted for:
    a. For the diagnosis of Ankylosing spondylitis, Crohn's disease, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis: 6 months
    b. For the diagnosis of Plaque psoriasis and Off Label indications (referenced in appendices): 3 months
2. Reauthorizations for all diagnoses will be granted for 12 months

Appendices

Appendix A: Examples of Traditional DMARDs

Traditional DMARDS*	
azathioprine	methotrexate*
cyclosporine	sulfasalazine*
hydroxychloroquine*	thalidomide
leflunomide	
If a member has a contraindication to **ALL** of the most commonly used traditional DMARDs* (methotrexate, sulfasalazine, and hydroxychloroquine), a trial with a traditional DMARD may be bypassed.	

Appendix B: Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	**Agents Used**
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix C: More frequent/Higher doses

Requests more frequent or higher doses of injectable biologics, may be approved if ALL of the following is provided:

1. Documentation of severe disease

2. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication*
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

*A trial with another injectable biologic may be bypassed if:

- The requested regimen is Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb), infliximab, Remicade® (infliximab), or Renflexis® (infliximab-abda) for Crohn's disease or ulcerative colitis and the request documents low drug levels and no/low antibodies. The recommended trough level for infliximab is greater than or equal to 5 mcg/mL in patients with inflammatory bowel disease.

Appendix D: Off Label Indications
Hidradenitis Suppurativa
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Paid claims or physician attestation of inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
4. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), provider provides clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
5. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab
6. Appropriate dosing: Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb), Remicade® (infliximab), or Renflexis® (infliximab-abda): 5 mg/kg on week 0, 2 and 6 then every 8 weeks,

Uveitis
Prescriber provides documentation of **ALL** of the following:

1. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **ALL** of the following:
    a. Ophthalmic (topical) or oral glucocorticoids
    b. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
    c. **ONE** of the following:
        i. Paid claims or physician attestation of Inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
        ii. Clinical rationale for use of Avsola® (infliximab-axxq), Remicade® (infliximab) Inflectra® (infliximab-dyyb), or Renflexis® (infliximab-abda) instead of Humira® (adalimumab)
    d. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)

e. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Scleritis
Prescriber provides documentation of **ALL** of the following:

1. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **ALL** of the following:
    a. Ophthalmic (topical) or oral glucocorticoids
    b. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
    c. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
    d. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Pulmonary Sarcoidosis
Prescriber provides documentation of **ALL** of the following:

1. Member has an appropriate diagnosis of sarcoidosis with pulmonary involvement
2. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **BOTH** of the following:
    a. Systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)
3. Prescriber must also document:
    a. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
    b. Clinical rationale for use of Avsola® (infliximab-axxq), unbranded infliximab, Remicade® (infliximab), Inflectra® (infliximab-dyyb), or Renflexis® (infliximab-abda) instead of Humira® (adalimumab)
5. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
6. 5. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Takayasu Arteritis (TAK)
Prescriber provides documentation of **ALL** of the following:

1. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **ALL** of the following:
    a. Systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)
2. Prescriber must also document **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to Humira® (adalimumab) and Enbrel® (etanercept)
    b. Clinical rationale for use of Avsola® (infliximab-axxq), unbranded infliximab, Remicade® (infliximab), Inflectra® (infliximab-dyyb), or Renflexis® (infliximab-abda) instead of Humira® (adalimumab) and Enbrel® (etanercept)

3. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
4. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

Neurologic Sarcoidosis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Paid claims or physician attestation of an inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids
3. Paid claims or physician attestation of an inadequate response or adverse reaction to **TWO** or a contraindication to **ALL** of the following:
    a. Azathioprine
    b. Cyclophosphamide
    c. Leflunomide
    d. Methotrexate
    e. Mycophenolate mofetil
4. For Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda), clinical rationale for use of the requested agent instead of unbranded infliximab and Avsola® (infliximab-axxq)
5. For BRAND NAME Remicade® (infliximab), the above criteria must be met and medical records must be provided documenting an inadequate response or adverse reaction to unbranded infliximab

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2. Renflexis (infliximab) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2017.
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Review History

11/17/2021 – Created and Reviewed Nov P&T; switched from CVS SGM to Custom criteria; matched with MH UPPL. Effective 01/01/2022
05/18/2022 – Updated and Reviewed for May P&T; Matched MH UPPL. Avsola and unbranded infliximab as preferred formulations of infliximab. A trial with other infliximab agents would require a step through one of these formulations. As unbranded infliximab is an authorized biosimilar to Remicade, a request for the latter agent would require a trial with unbranded infliximab. UC criteria: Requirement of provider specialty was removed, required trial with one anti-TNF agent and Entyvio was removed, and "Member is not currently receiving concomitant therapy with immunomodulators or biologic agents" was removed. Appendix C: Off label indications was updated. Renamed Appendix B to "Conventional Therapies for Plaque Psoriasis". Effective 07/01/2022.
06/22/2022 - Reviewed and updated for June P&T; matched MH UPPL. Added off label indication of neurologic sarcoidosis to Appendix section. Effective 08/01/2022.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Clinical rationale for use of Inflectra or Renflexis instead of unbranded infliximab or Avsola updated to include clinical rationale instead of both agents. Added criteria for off label use in Neurologic Sarcoidosis. Effective 11/01/2022

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