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

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

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

Coverage Guidelines

Authorizations requests will be reviewed on a case by case basis for members new to AllWays Health Partners 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®

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®

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** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing
4. Provider provides clinical rationale for use of the requested agent instead of Enbrel® and Humira®

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 conventional therapy** (see appendix)
        a. topical agent
        b. phototherapy
        c. systemic agent
    b. Contraindication to **ALL conventional therapies**:
        a. topical agents
        b. phototherapy
        c. systemic agents
    c. 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®

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 Enbrel® and Humira®

Fistulizing Crohn's disease

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

1. Appropriate diagnosis
2. Appropriate dosing (see appendix and availability and dosage section) †

Moderate-to-severe Ulcerative colitis

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

1. Appropriate diagnosis
2. Prescriber is a gastroenterologist or consult notes from a gastroenterology office are provided
3. Member meets **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for ulcerative colitis
    b. Contraindication to **ALL** anti-TNF agents
4. The member has had inadequate response, adverse reaction, or contraindication to Entyvio®
5. Appropriate dosing
6. Member is not currently receiving concomitant therapy with immunomodulators or biologic agents

Continuation of Therapy

Resubmission by prescriber for any of the following FDA-approved diagnoses 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: 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: Off-Label Indications

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), 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.

Hydradenitis Supprativa
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. 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)

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. Opthalmic (topical) or oral glucocorticoids
    b. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)

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 **ALL** of the following:
    a. Systemic glucocorticoids
    b. **ONE** traditional DMARD (methotrexate, azathioprine, leflunomide, or mycophenolate)
    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)

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)
    c. ONE of the following:
        i. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to Humira® (adalimumab) and Enbrel® (etanercept)
        ii. Clinical rationale for use of Avsola® (infliximab-axxq), Remicade® (infliximab) Inflectra® (infliximab-dyyb), or Renflexis® (infliximab-abda) instead of Humira® (adalimumab) and Enbrel® (etanercept)

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2. Renflexis (infliximab) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme; November 2017.
3. Inflectra (infliximab dyyb) [prescribing information]. New York, NY: Pfizer; 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

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.