Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016O.1221	**MISCELLANEOUS AGENTS** **THERAPEUTIC IMMUNOMODULATORS (TIMs)** See Table 1 for Applicable Medications
Effective Date: 1/1/2022 **Robert Gluckman, M.D.** **Chief Medical Officer**	Review/Revised Date: 01/17, 08/17, 9/17, 01/18, 05/18, 07/18, 08/1, 11/18, 10/19, 3/19, 4/19, 08/19, 09/19, 01/20, 08/20, 09/20, 01/21, 05/21, 09/21, 11/21 (JLS) P&T Committee Meeting Date: 02/17, 08/17, 10/17, 02/18, 06/18, 08/18, 10/18, 12/18, 02/19, 04/19, 06/19, 08/19, 10/19, 02/20, 08/20, 10/20, 02/21, 06/21, 10/21, 10/21 (CV), 12/21 Original Effective Date: 03/17 Approved by: Oregon Region Pharmacy and Therapeutics Committee Page 1 of 16

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Medicaid

POLICY CRITERA:

COVERED USES:
Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

REQUIRED MEDICAL INFORMATION:
1. For **all requests**, the patient must have an FDA labeled indication for the requested agent and is a covered indication according to the Prioritized List of Health Care Services.

AND
2. The requested agent will not be given concurrently with another therapeutic immunomodulator agent or apremilast (Otezla®)

AND
3. One of the following:
    a. For patients established on the requested therapeutic immunomodulator, the following criteria must be met. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.

i. For Hidradenitis Suppurativa, continuation of adalimumab therapy may be covered with clear evidence of response, defined as BOTH of the following:
   1. A reduction of 25% or more in the total abscess and inflammatory nodule count, AND
   2. No increase in abscesses and draining fistulas

ii. For Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis:
   1. Documentation that patient is adherent to both TIMs agent and DMARD (if DMARD therapy has been prescribed in conjunction with the biologic therapy)
   2. Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

iii. For all other indications: Documentation of response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

b. Patients not established on the requested therapeutic immunomodulator must meet ALL of the following criteria:
   i. Requests for non-preferred infliximab product (Remicade® or Avsola®) will require failure, intolerance, or contraindication to the preferred infliximab biosimilar products (Inflectra® and Renflexis®), in addition the indication-specific criteria below.
   ii. For **Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis**, all of the following criteria (1-3) must be met:
      1. Use of disease-modifying anti-rheumatic drugs (DMARDs):
         a. Documented inadequate response to at least one of the following disease-modifying antirheumatic drugs (DMARDs) after at least six months of therapy: methotrexate, leflunomide, sulfasalazine or hydroxychloroquine

         OR

         b. Documented intolerance or contraindication to all of the above DMARDs (i.e., methotrexate, leflunomide, sulfasalazine and hydroxychloroquine)
      2. Documentation that the patient is currently using a DMARD and will continue concomitant use (unless contraindicated).
      3. Preferred products (adalimumab, etanercept, infliximab biosimilars Inflectra® and Renflexis®) may be covered. For non-preferred TIMs agent:

a. Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to at least one of the following preferred TIMs agents: adalimumab (Humira®), etanercept (Enbrel®), or preferred infliximab biosimilar (Inflectra® or Renflexis®)

iii. For **inflammatory bowel diseases** (e.g. Crohn's disease, ulcerative colitis), all of the following criteria (1 and 2) must be met:

1. Use of conventional immunosuppressive therapies:
   a. Documented inadequate response to at least one of the following conventional immunosuppressive therapies for at least six months: mercaptopurine, azathioprine, or budesonide

   OR

   b. Documented intolerance or contraindication to these therapies

   OR

   c. Medical rationale is provided for escalating to biologic therapy without previous trial of conventional therapies (e.g., severity of disease activity)
2. Preferred products [(adalimumab, infliximab biosimilars (Inflectra® and Renflexis®), or vedolizumab (for ulcerative colitis)] may be covered. For non-preferred TIMs agent: documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to at least **two** of the following TIMs agents:
   a. Adalimumab (Humira®)
   b. Preferred infliximab biosimilar (Inflectra® or Renflexis®)
   c. vedolizumab (Entyvio®)

iv. For **psoriasis**, all of the following criteria (1-3) must be met:

1. Patient must have severe disease, as defined by both of the following:
   a. Documentation of functional impairment as indicated by Dermatology Life Quality Index (DLQI) score of at least 11, Children's Dermatology Life Quality Index (CDLQI) score of at least 13, or severe score on other validated tool
   b. At least one of the following:
      i. At least 10% of body surface area involve

ii. Hand, foot or mucous membrane involvement

2. Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to each of the following first-line agents:
    a. Topical high-potency corticosteroids (e.g., betamethasone 0.05%, clobetasol 0.05%, fluocinonide 0.05%, halcinonide 0.1%, halobetasol propionate 0.05%, triamcinolone 0.5%)
    b. Another topical agent (e.g., calcipotriene, tazarotene)
    c. Phototherapy
    d. Systemic therapy (e.g., methotrexate, cyclosporine)
3. Preferred products (adalimumab, etanercept, infliximab biosimilars Inflectra® and Renflexis®, or secukinumab) may be covered. For non-preferred TIMs agent: Documented adequate trial and failure (after at least three months of therapy), intolerance or contraindication to the following preferred agents:
    a. One of the following TNF inhibitor agents: adalimumab (Humira®) or preferred infliximab biosimilar (Inflectra® or Renflexis®)

    AND

    b. Secukinumab (Cosentyx®)

v. For **ankylosing spondylitis**, preferred agents (adalimumab, infliximab biosimilars Inflectra® and Renflexis®, or etanercept) may be covered:
1. For non-preferred TIMs agent: Documented trial and failure (after at least three months of therapy), intolerance or contraindication to at least one of the following preferred agents: adalimumab (Humira®), etanercept (Enbrel®) or preferred infliximab biosimilar (Inflectra® or Renflexis®)

vi. For **Hidradenitis Suppurativa**, adalimumab (Humira®) may be covered if the following criteria are met:
1. Documentation of moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III)
2. Documented inadequate response to at least one conventional therapy after 90 days of therapy (e.g., oral antibiotics) unless contraindicated or not tolerated

vii. For **all other indications**, the requested agent may be covered if FDA approved for the indication and age of the patient.

Note:

- Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator agent
- Conventional therapy and preferred agent requirements may be waived with clinically appropriate medical rationale

For quantity limit exception requests (See Appendix 1 for specific quantity limits)

1. For patients already established on the requested dose and frequency, the following criteria must be met: Documentation of response to therapy with increased dosing. Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy.
2. For patients not established on requested dose and frequency (e.g., requesting dose escalation), **one** of the following criteria must be met:
3. For patients not established on requested dose and frequency (e.g., requesting dose escalation, previous dose escalation sponsored by manufacturer not previously approved by a health plan), one of the following must be met:
    a. Requested dose is FDA-labeled for the indication. For example:
        i. For Crohn's disease: Stelara® will be approved for FDA-labeled dosing for this condition (90 mg every eight weeks)
        ii. For Hidradenitis Suppurativa: Humira® will be approved for FDA-labeled dosing for this condition (40 mg once weekly)
        iii. For psoriasis: Cimzia® will be approved for FDA-labeled dosing for this condition (800 mg every four weeks)
        iv. For ulcerative colitis: Simponi® will be approved for FDA-labeled dosing for this condition (100 mg every 28 days)
    b. For requests for dose escalation in inflammatory bowel disease (i.e., Crohn's disease or ulcerative colitis), adalimumab 40 mg once weekly or ustekinumab 90 mg every six weeks may be covered if all of the following criteria are met:
        i. Documentation that patient initially responded to the medication, but has experienced an inadequate response, or waning of response, to the medication. Patient must have used the medication at the FDA-labeled dosing for at least six months.
        ii. Documentation of current and active inflammation on endoscopy or imaging [such as computed tomography enterography (CTE) or magnetic resonance enterography (MRE)] obtained after at least six (6) months of treatment on the

FDA-approved dosing outlined above. Results must have been obtained within the last six months prior to this request.

c. For other disease states: requests for dose escalation are considered experimental/investigational and are not covered

EXCLUSION CRITERIA:

1. Below the line diagnoses
2. Combination therapy with another therapeutic immunomodulator (TIM) agent or apremilast (Otezla®)

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

- Prior Authorization: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes
- Quantity Limitation: Initial authorization will be approved for six months. Reauthorization will be approved for one year.
    - Exception: Authorization for FDA-approved dosing above the quantity limit will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Therapeutic Immunomodulators (TIMs) have become standard of care in patients with moderate to severe, chronic inflammatory diseases where conventional therapies have not been adequate. These agents work by targeting specific steps in the inflammatory and immune cascade.

FDA APPROVED INDICATIONS:

Table 1. Therapeutic immunomodulators (TIMs) requiring prior authorization and their respective FDA-approved Indications. FDA approvals listed below are for adult patients, unless otherwise indicated.

Drug	MOA	RA	CD	UC	Ps	PsA	AS	Other
Abatacept (Orencia®)	T-cell inhibitor	X				X		PJIA (age 2+)
Adalimumab (Humira®)	Anti-TNF	X	X	X*	X	X	X	Uveitis (age 2+), HS (age 12+), PJIA (age 2+)
Anakinra (Kineret®)	IL-1 inhibitor	X						NOMID/ CAPS (age 0+), DIRA
Apremilast (Otezla®)	PDE-4 inhibitor				X	X		BD
Baricitinib (Olumiant®)	JAK Inhibitor	X						
Brodalumab (Siliq®)	IL-17 inhibitor				X			
Certolizumab (Cimzia®)	Anti-TNF	X	X**		X	X	X	NRAS
Etanercept (Enbrel®)	Anti-TNF	X			X (age 4+)	X	X	PJIA (age 2+)
Golimumab (Simponi®)	Anti-TNF	X		X*		X (age 2+)	X	PJIA (age 2+)
Guselkumab (Tremfya®)	IL-23 inhibitor				X	X		
Infliximab (Remicade®)	Anti-TNF	X	X (age 6+)	X* (age 6+)	X	X	X	
Infliximab-dyyb (Inflectra®)	Anti-TNF	X	X (age 6+)	X* (age 6+)	X	X	X	
infliximab-abda (Renflexis®)	Anti-TNF	X	X (age 6+)	X* (age 6+)	X	X	X	
infliximab-axxq (Avsola®)	Anti-TNF	X	X (age 6+)	X* (age 6+)	X	X	X	

Drug	MOA	RA	CD	UC	Ps	PsA	AS	Other
Ixekizumab (Taltz®)	IL-17 inhibitor				X (age 6+)	X	X	NRAS
Risankizumab-rzaa (Skyrizi®)	IL-23 Inhibitor				X			
Sarilumab (Kevzara®)	IL-6 inhibitor	X						
Secukinumab (Cosentyx®)	IL-17 inhibitor				X	X	X	NRAS
Tildrakizumab-asmn (Ilumya®)	IL-23 inhibitor				X			
Tocilizumab (Actemra®)	IL-6 inhibitor	X						GCA, CRS (age 2+), PJIA/SJIA (age 2+), SSc-ILD
Tofacitinib (Xeljanz® and Xeljanz XR®)	JAK inhibitor	X		X		X		PJIA (age 2+)
Upadacitinib (Rinvoq®)	JAK inhibitor	X						
Ustekinumab (Stelara®)	IL-12/23 inhibitor		X**	X	X (age 6+)	X		
Vedolizumab (Entyvio®)	α4β7 inhibitor		X**	X*				

*Does not have FDA indication for pediatric ulcerative colitis
**Does not have FDA indication for pediatric Crohn's disease
Abbreviations: MOA = mechanism of action; JAK = Janus kinase; IL = interleukin; PDE-4 = Phosphodiesterase 4; RA = rheumatoid arthritis; SJIA = Systemic juvenile idiopathic arthritis; PJIA = Polyarticular Juvenile Idiopathic Arthritis CD = Crohn's disease; UC = ulcerative colitis; Ps = psoriasis; PsA = psoriatic arthritis; AS = ankylosing spondylitis; HS = Hidradenitis Suppurativa; NOMID/CAPS = neonatal onset multi-systemic inflammatory disease/Cryopyrin-Associated Periodic Syndromes; BD = oral ulcers associated with Behçet's Disease; GCA = giant cell arteritis; CRS = cytokine release syndrome; NRAS = non-radiographic axial spondyloarthritis; DIRA = Deficiency of Interleukin-1 Receptor Antagonist; SSc-ILD = systemic sclerosis-associated interstitial lung disease

POSITION STATEMENT:

Due to lack of extensive comparative "head-to-head" clinical trials with these agents, comparisons are typically based on indirect comparative evidence.

Inflammatory Bowel Disease

Crohn's Disease (CD)

Based on the available evidence and national practice guidelines, TIMs are effective agents in inducing and maintaining remission in severe, active CD. These agents are typically used when conventional therapies (e.g.,

corticosteroids, mesalamine, 6-MP and azathioprine) have failed to induce remission. Some systematic reviews and meta-analyses suggest that infliximab and adalimumab may have superior efficacy over other TIMs agents from indirect comparisons. Overall, there is insufficient direct comparative evidence for the efficacy of TIMs in the treatment of severe, active CD, all FDA approved agents have shown to be superior to placebo and are considered to have comparable efficacy.

Dose escalation requests are common for this disease state. Adalimumab (Humira®) maintenance dosing is every other week, but evidence suggests that once weekly dosing can be helpful for patients that have not achieved a full response to every other week dosing (this dosing regimen is covered per policy). Ustekinumab (Stelara®) is covered at every eight (8) weeks for CD, Two recent retrospective evaluations of patients that were dose escalated to every four (4) weeks have been published.[3,4] However, these studies are of low-quality; retrospective in nature (non-standardized treatment protocols and follow-up procedures) and did not adequately compare changes seen with dose escalation to that of standard therapy. In addition, surrogate markers were used for determining disease activity (lack of robust endoscopic evaluations). Endoscopy/colonoscopy and/or imaging are used to measure active inflammation and can be useful in determining whether dose escalation is reasonable. Per the American College of Gastroenterology (ACG) 2018 Clinical Guideline on the Management of Crohn's Disease in Adults, endoscopy/colonoscopy may show evidence of ulcerations and granulomatous inflammation. Common forms of imaging in Crohn's disease are computed tomography enterography (CTE) and magnetic resonance enterography (MRE). Signs of active inflammation through on CTE consist of mucosal enhancement, mesenteric hypervascularity, and mesenteric fat stranding. In MRE, the signs are similar to CTE, but also can detect wall enhancement, mucosal lesions, and T2 hypersensitivity.

Ulcerative Colitis (UC)

Based on the available evidence and national practice guidelines, TIMs are effective agents in inducing and maintaining remission in moderate to severe UC. These agents are typically used when conventional therapies (e.g., aminosalicylates, topical mesalamine, corticosteroids, 6-mercaptopurine (6-MP) and azathioprine) have failed to induce remission. Infliximab may be more consistently efficacious for inducing remission and mucosal healing than adalimumab. Vedolizumab is a non-anti-TNF therapy option for the treatment of UC. Overall, there is insufficient direct comparative evidence for the

efficacy of TIMs in the treatment of moderate to severe UC, all FDA approved agents have shown to be superior to placebo and are considered to have comparable efficacy.

In 2020, the Institute for Clinical and Economic Review (ICER) published a report on TIMs for UC, assessing the following therapies: adalimumab, golimumab, infliximab and biosimilars, tofacitinib, and ustekinumab. All agents were found to be clinically superior than placebo, and all were found to be comparable to adalimumab. It was noted that vedolizumab was "found to produce greater rates of clinical response and remission over adalimumab, the market leader, in both patients who had used TIMs previously ("biologic-experienced") as well as those who did not ("biologic-naïve")." No agents were found to be cost-effective at current drug costs, but infliximab and its biosimilars represent the best value for money for UC.

Guidelines:

- American Gastroenterological Association: http://www.gastro.org/guidelines
- American College of gastroenterology: https://gi.org/clinical-guidelines/clinical-guidelines-sortable-list/

Rheumatologic Disorders

Rheumatoid arthritis (RA)

Based on the available evidence and national practice guidelines, TIMs are effective agents in treating moderate to severe RA. These agents are typically used when non-biologic disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate, have failed. There is limited and/or insufficient direct comparative evidence for the efficacy of TIMs in the treatment of moderate to severe RA, all FDA approved agents have shown to be superior to placebo.

In 2017, ICER published a review of the Targeted Immune Modulators for Rheumatoid Arthritis. They reviewed the following therapies:

- TNFα inhibitors: adalimumab (Humira®), certolizumab pegol (Cimzia®), etanercept (Enbrel®), golimumab (Simponi® and Simponi Aria®), infliximab (Remicade®):
- CD20-directed cytolytic B-cell antibody: rituximab (Rituxan®)
- T-cell inhibitor: abatacept (Orencia®)
- IL-6 inhibitors: tocilizumab (Actemra®,), sarilumab (Kevzara™)
- JAK inhibitors: tofacitinib (Xeljanz®), baricitinib (Olumiant™)

Newer agents, such as upatacitinib (rinvoq®) were not included in this review.

Using a network meta-analysis, the review suggests that all agents are superior to conventional DMARD monotherapy. There have been some head-to-head trials conducted between the TIMs agents and adalimumab was found to be inferior to monotherapy with tocilizumab or sarilumab in terms of achieving clinical remission or ACR responses; these agents were rated as B+ over adalimumab (Moderate certainty of a small or substantial net health benefit, with high certainty of at least a small net health benefit). Abatacept was given the same B+ rating over infliximab. Tofacitinib is considered more costly and less effective than adalimumab.

In 2019, ICER completed a review of janus kinase (JAK) inhibitors for the treatment of RA. They found that upadacitinib and tofacitinib have a high certainty of net health benefit over DMARD monotherapy in patients that have not used a TIMs agent previously; the certainty of this benefit is lower when patients have already failed a TIMs agent. Upadacitinib may have superior efficacy to adalimumab and may be more cost-effective, but noted that adalimumab is still well above cost-effectiveness thresholds. Additionally, there are safety concerns with JAK inhibitors medications that must be taken into consideration

Juvenile Idiopathic Arthritis (JIA), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA)

Based on the available evidence and national practice guidelines, TIMs are effective agents in treating these conditions. There is limited and/or insufficient direct comparative evidence for the efficacy of TIMs in these conditions, all FDA approved agents have shown to be superior to placebo and are considered to have comparable efficacy.

Guidelines:

- American College of Rheumatology: https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines

Dermatologic Disorders

Plaque psoriasis (Ps)

Based on the available evidence and national practice guidelines, TIMs are effective agents in treating moderate to severe plaque psoriasis and are generally initiated when standard conventional therapies (e.g., topical therapy and phototherapy) are inadequate. Low quality evidence suggests that

ustekinumab, secukinumab, and ixekizumab may have better efficacy than etanercept, but there were sufficient limitations identified to render the evidence of uncertain validity. Secukinumab and brodalumab may have better efficacy than ustekinumab with reference to Psoriasis Area Severity Index (PASI) 90 and 100. Brodalumab has significant safety concerns that limit its usability. At this time, all FDA approved agents have shown to be superior to placebo and are considered to have comparable efficacy.

Guidelines:

- American Academy of Dermatology: https://www.aad.org/practicecenter/quality/clinical-guidelines

Immune checkpoint inhibitor (ICI) related diarrhea/colitis

Diarrhea and colitis are common symptoms of treatment with ICI therapy. This side effect can present as watery diarrhea, cramping, and fecal urgency. The National Comprehensive Cancer Network (NCCN) recommends that for moderate diarrhea/colitis (G2), ICI therapy be held and the patient be given prednisone/methylprednisolone at 1 mg/kg/day. If there is no improvement in 2-3 days, increase steroids to 2 mg/kg/day and consider addition of infliximab. For patients with severe diarrhea/colitis (G3-4), hold ICI therapy (discontinue for G4), consider whether inpatient care is necessary to provide adequate supportive care, and start prednisone/methylprednisolone at 2 mg/kg/day. If no improvement in two days, consider addition of infliximab. Vedolizumab may be considered in patients that have infliximab-refractory diarrhea/colitis.

REFERENCE/RESOURCES:

1. Relevant package inserts
2. Ollech, JE, Normatov I, Peleg N et al. Effectiveness of Ustekinumab Dose Escalation in Patients With Crohn's Disease. Clin Gastroenterol Hepatol. 2020;S1542-3565(20)30205-6. doi: 10.1016/j.cgh.2020.02.035.
3. Kopylove U, Hanzel J, Liefferinckx C et al. Effectiveness of ustekinumab dose escalation in Crohn's disease patients with insufficient response to standard-dose subcutaneous maintenance therapy. Aliment Pharmacol Ther. 2020 Jul;52(1):135-142. doi: 10.1111/apt.15784.
4. Institute for Clinical and Economic Review (ICER). Rheumatoid Arthritis: Final Report. Available at https://icer-review.org/material/ra-final-report/ (Accessed September 16, 2020)
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https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf (Accessed September 16, 2020)

6. Oregon State University Drug Use Research & Management Program. Drug Class Update: Targeted Immune Modulators for Autoimmune Diseases. Available at https://www.orpdl.org/durm/meetings/meetingdocs/2021_10_07/finals/BiologicsAutoimmune_ClassUpdate.pdf (Accessed September 14, 2021)
7. ICER. Rheumatoid Arthritis: An assessment of JAK inhibitors. Available at https://icer.org/assessment/rheumatoid-arthritis-2019/ (Accessed September 14, 2021)
8. ICER. An assessment of treatments for ulcerative colitis. Available at https://icer.org/assessment/ulcerative-colitis-2020/ (Accessed September 14, 2021)
9. National Comprehensive Cancer Network (NCCN). NCCN Guidelines Management of Immunotherapy-Related Toxicities Version 3.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf (Accessed September 14, 2021)

Appendix 1.
Quantity limitations for self-administered medications

Drug	Quantity Limit
Abatacept (Orencia®)	4 doses per 28 days
Adalimumab (Humira®)	2 doses per 28 days
Anakinra (Kineret®)	30 syringes per 30 days
Apremilast (Otezla®)	60 tablets per 30 days
Baricitinib (Olumiant®)	30 tablets per 30 days
Brodalumab (Siliq®)	2 injections per 28 days
Certolizumab (Cimzia®)	1 kit per 28 days
Etanercept (Enbrel®)	200 mg per 28 days
Golimumab (Simponi®)	1 dose per 28 days
Guselkumab (Tremfya®)	1 dose every 56 days
Ixekizumab (Taltz®)	1 dose per 28 days
Risankizumab-rzaa (Skyrizi®)	150 mg per 84 days
Sarilumab (Kevzara®)	1.66 mL (2 injections) per 28 days
Secukinumab (Cosentyx®)	300 mg per 28 days
Tildrakizumab-asmn (Ilumya®)	100 mg per 84 days
Tocilizumab (Actemra®)	4 doses per 28 days
Tofacitinib (Xeljanz® and Xeljanz XR®)	IR: 60 tablets per 30 days ER: 30 tablets per 30 days
Ustekinumab (Stelara®)	1 dose per 84 days

Appendix 2.
Contraindication(s) for TIMs agents

TIMs Agent	Contraindication(s)
Abatacept (Orencia®)	None
Adalimumab (Humira®)	None
Anakinra (Kineret®)	Hypersensitivity to *E coli* proteins
Baricitinib (Olumiant®)	None
Brodalumab (Siliq®)	Crohn's disease
Certolizumab (Cimzia®)	None
Etanercept (Enbrel®)	Sepsis
Golimumab (Simponi/Simponi Aria®)	None
Guselkumab (Tremfya®)	None

TIMs Agent	Contraindication(s)
Infliximab (Remicade®)	Doses > 5 mg/kg in moderate to severe heart failure; hypersensitivity reaction to Remicade®, its inactive components, or to any murine proteins
Infliximab-abda (Renlfexis®)	Doses >5 mg/kg in moderate to severe heart failure; previous severe hypersensitivity reaction to infliximab products or known hypersensitivity to inactive components of Renflexis® or to any murine proteins
Infliximab-dyyb (Inflectra®)	Doses >5 mg/kg in moderate to severe heart failure; Previous severe hypersensitivity reaction to infliximab products, or known hypersensitivity to inactive components of Inflectra® or to any murine proteins
Ixekizumab (Taltz®)	Previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients
Risankizumab-rzaa (Skyrizi®)	None
Sarilumab (Kevzara®)	Known hypersensitivity to sarilumab or any of the inactive ingredients.
Secukinumab (Cosentyx®)	Serious hypersensitivity reaction to secukinumab or to any of the excipients
Tildrakizumab-asmn (Ilumya®)	Serious hypersensitivity reaction to tildrakizumab or to any of the excipients
Tocilizumab (Actemra®)	Hypersensitivity to Actemra®
Tofacitinib (Xeljanz® and Xeljanz XR®)	None
Ustekinumab (Stelara®)	Clinically significant hypersensitivity to ustekinumab or to any of the excipients
Vedolizumab (Entyvio®)	Known serious or severe hypersensitivity reaction to Entyvio® or any of its excipients

Appendix 3. Coding for medically infused therapies

Drug	HCPCS Code

Preferred Agents	
Infliximab-dyyb (Inflectra®)	Q5103
Infliximab-abda (Renflexis®)	Q5104
Non-Preferred Agents[t]	
Infliximab (Remicade®)	J1745
Infliximab-axxq (Avsola®)	Q5121
tocilizumab (Actemra®)	J3262
vedolizumab (Entyvio®)	J3380
abatacept (Orencia®)	J0129
tildrakizumab-asmn (Ilumya®)	J3245
golimumab IV (Simponi Aria®)	J1602
ustekinumab (Stelara®)	J3358