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Subject: Risankizumab-rzaa (Skyrizi®) Injection and Infusion

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DESCRIPTION:

Risankizumab-rzaa (Skyrizi) is an injectable humanized IgG1 monoclonal antibody that selectively inhibits interleukin-23 (IL-23) by binding to the p19 subunit. It was initially approved by the US Food and Drug Administration (FDA) in May 2019 for “the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy”. In January 2022, the FDA approved the new indication of active psoriatic arthritis in adults. In June 2022, the FDA approved an additional new indication for the treatment of moderately to severely active Crohn's disease (CD) in adults. This approval also introduced the availability of intravenous (IV) risankizumab (previously only available as a subcutaneous injection) since the treatment of CD requires three IV induction doses. Also, a new subcutaneous dosage of 360 mg given via on-body injector was introduce for the CD indication. A second on-body injector dosage of 180 mg was introduced a few months later. Risankizumab was the third IL-23 to be approved by the FDA [following guselkumab (Tremfya]) in July 2017 and tildrakizumab (Ilumya) in March 2018]; however, it is the first IL-23 to be approved for the treatment of an inflammatory bowel disease. Interleukin-23 is a naturally occurring cytokine that is involved in inflammatory and immune response, and its blockade inhibits the release of proinflammatory cytokines and chemokines. Skyrizi, as sponsored by the innovator drug company, was granted an orphan drug designation for treatment of pediatric Crohn's disease in November 2016.

DERMATOLOGICAL DISORDERS

Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful.

Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.

The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:

- Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
    - Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
    - Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
- Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
    - Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
    - 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
- Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin

The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (great than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when is occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus. The AAD psoriasis treatment guidelines recommend the following:

- Limited disease (less than 5% of BSA):
    - Topical corticosteroids are first line as either monotherapy or in conjunction with non-steroidal topical agents
    - Vitamin D analogs, calcipotriene, calcipotriol, and calcitriol, are other first line agents and are often used in combination with topical corticosteroids
    - Tazarotene is a corticosteroid sparing agent and can be used in combination with topical corticosteroids to produce a synergistic effect and longer durations of treatment benefit and remission
    - Phototherapy is another first line option for limited disease, and allows for selective targeting of localized lesions and resistant areas such as the scalp and skin folds, leaving surrounding, non-lesional skin unaffected
    - Calcineurin inhibitors (tacrolimus and pimecrolimus) may also be considered first line for intertriginous, inverse, face, and genital psoriasis
    - Systemic agents are considered second line and only for short term use

- Moderate to severe disease without PsA (more than 5% of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
    - UV-therapy is considered first line as monotherapy or in combination with acitretin or MTX
    - If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
    - Second line systemic agents include leflunomide, sulfasalazine, and tacrolimus
- Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA

The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:

- The preferred assessment instrument for determining disease severity is BSA
- Target response after treatment initiation should be BSA ≤1% after 3 months
- Acceptable response is either a BSA ≤3% or a BSA improvement ≥75% from baseline at 3 months after treatment initiation

RHEUMATOID DISORDERS

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.

The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.

The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
    - Actively inflamed joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Active skin and/or nail involvement
    - Extraarticular manifestations such as uveitis or inflammatory bowel disease

- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
- Severe PsA disease includes the presence of 1 or more of the following:
    - Erosive disease
    - Elevated markers of inflammation (ESR, CRP) attributable to PsA
    - Long-term damage that interferes with function (i.e., joint deformities)
    - Highly active disease that causes a major impairment in quality of life
    - Active PsA at many sites including dactylitis, enthesitis
    - Function limiting PsA at a few sites
    - Rapidly progressive disease
- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
    - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor
        - Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis
    - Previous treatment with OSM and continued active disease:
        - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
        - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy
        - Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy
    - Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease:
        - Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic

INFLAMMATORY BOWEL DISEASE

Crohn's Disease (CD)

Crohn's Disease (CD) is an inflammatory condition that can affect any portion of the gastrointestinal tract from the mouth to the perianal area. Choice of therapy is dependent on the anatomic location of disease, the severity of disease, and whether the treatment goal is to induce remission or maintain remission. The American Gastroenterological Association (AGA) 2021 guideline recommends the following:

- Biologic therapy:
    - The AGA suggest early introduction with a biologic, with or without an immunomodulator, rather than delaying their use until after failure of 5-aminosalicylates and/or corticosteroids
    - Anti-TNF (i.e., infliximab or adalimumab) and ustekinumab are recommended over no treatment for the induction and maintenance of remission
    - Vedolizumab is suggested over no treatment for the induction and maintenance of remission
    - AGA suggests against the use of natalizumab over no treatment for the induction and maintenance of remission
    - Patients naïve to biologic therapy, the AGA recommends infliximab, adalimumab, or ustekinumab over certolizumab pegol and suggests the use of vedolizumab over certolizumab pegol for the induction of remission
    - Patients with primary non-response to anti-TNF, the AGA recommends ustekinumab and suggests vedolizumab for induction of remission
    - Patients with secondary non-response to infliximab, the AGA recommends use of adalimumab or ustekinumab and suggests the use of vedolizumab for the induction of remission (if adalimumab was the first line drug, there is indirect evidence to suggest using infliximab as a second-line agent)
- DMARD therapy:
    - Corticosteroids are suggested over no treatment for the induction of remission, and are recommended against for maintenance of remission
    - Patients in corticosteroid induced remission or with quiescent moderate to severe CD, the AGA suggests thiopurines for maintenance of remission
    - Subcutaneous or intramuscular methotrexate are suggested over no treatment for the induction and maintenance of remission
    - The AGA recommends against the use of 5-aminosalicylates or sulfasalazine over no treatment for the induction or maintenance of remission
    - The AGA suggests against the use of thiopurines over no treatment for achieving remission and recommends biologic drug monotherapy over thiopurine monotherapy for induction of remission
    - The AGA suggests against the use of oral methotrexate monotherapy over no treatment for the induction and maintenance of remission
- Combination therapy:
    - Patients that are naïve to biologics and immunomodulators, the AGA suggest use of infliximab in combination with thiopurines over infliximab monotherapy for the induction and maintenance

of remission (combination infliximab with methotrexate may be more effective over infliximab monotherapy)

- Patients that are naïve to biologics and immunomodulators, the AGA suggest use of adalimumab in combination with thiopurines over adalimumab monotherapy for the induction and maintenance of remission (combination adalimumab with methotrexate may be more effective over adalimumab monotherapy)
- No recommendations are being made regarding the use of ustekinumab or vedolizumab in combination with thiopurines or methotrexate over biologic monotherapy for induction or maintenance or remission

The 2018 American College of Gastroenterology (ACG) guidelines recommend the following:

- Mild to moderately severe disease/low risk disease:
  - Sulfasalazine (in doses of 3-6 grams daily) is effective in colonic and/or ileocolonic CD, but not those with isolated small bowel disease
  - 5-aminosalicylic (ASA) suppositories and enema preparations are effective for induction and maintenance of remission in rectal and sigmoid disease
  - Conventional corticosteroids are primarily used for the treatment of flares, and are often used as a bridge until immunomodulators and/or biologic agents become effective
  - Controlled ileal release budesonide is effective for induction of remission in ileocecal disease
- Moderate to severe disease/moderate to high-risk disease
  - Corticosteroids are effective for short-term use in alleviating signs and symptoms of moderate to severely active CD, but do not induce mucosal healing and should be used sparingly
  - Azathioprine, 6-mercaptopurine, or MTX (15 mg once weekly) may be used in treatment of active disease and as adjunctive therapy for reducing immunogenicity against biologic therapy
  - TNF inhibitors should be used to treat CD that is resistant to treatment with corticosteroids and that is refractory to thiopurines or MTX
  - Vedolizumab with or without an immunomodulator should be considered for induction of symptomatic remission for patients with moderate to severely active CD and objective evidence of active disease
  - Ustekinumab should be used in patients that have failed previous treatment with corticosteroids, thiopurines, MTX, or TNF inhibitors, or in patients with no prior TNF inhibitor exposure
- Severe/fulminant disease:
  - IV corticosteroids should be used
  - TNF inhibitors can be considered
- Maintenance therapy:
  - Thiopurines or methotrexate should be considered once remission is induced with corticosteroids

- TNF inhibitors, specifically infliximab, adalimumab, and certolizumab pegol, should be used in combination with azathioprine, MTX, or 6-mercaptopurine to maintain remission of TNF induced remission
- Vedolizumab should be used for maintenance of remission of vedolizumab induced remission
- Ustekinumab should be used for maintenance of remission of ustekinumab induced remission

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: The self-administered products with prerequisites for certain indications are as follows:

Table 1

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL,	Oral: Xeljanz	SQ: Actemra (Amjevita 10 mg/0.2 mL,	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**,

	Amjevita 40 mg/0.8 mL, Enbrel, Hadlima, Humira		Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira is a required Step 1 agent)			Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Humira, Hadlima, **Skyrizi**, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Rheumatoid Arthritis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Dermatological Disorders						
Hidradenitis Suppurativa (HS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**

Psoriasis (PS)	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Cosentyx, Enbrel, Hadlima, Humira, **Skyrizi**, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz, Yuflyma**, Yusimry** Oral: Sotyktu
Inflammatory Bowel Disease						
Crohn's Disease	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, **Skyrizi**, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira are required Step 1 agents)	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Ulcerative Colitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, or Humira is a required Step 1 agent)	N/A	Zeposia (Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Entyvio, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**

						Oral: Velsipity
Other						
Uveitis	SQ: Amjevita 10 mg/0.2 mL, Amjevita 20 mg/0.4 mL, Amjevita 40 mg/0.8 mL, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita 20 mg/0.2 mL**, Amjevita 40 mg/0.4 mL**, Amjevita 80 mg/0.8 mL**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators						
Alopecia Areata (AA) Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)	N/A	N/A	N/A	N/A	N/A	N/A

***Note**: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product

****Note**: Amjevita (one of: 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL), Hadlima, and Humira are required Step 1 agents

Note: Branded generic available for Cyltezo, Hulio, Hyrimoz, and Idacio and are included as a target at same step level in this program

SUBCUTANEOUS SKYRIZI (PHARMACY BENEFIT)

Initiation of subcutaneous risankizumab (Skyrizi) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. **ONE** of the following ("a", "b", or "c"):
    a. Information has been provided that indicates the member has been treated with subcutaneous risankizumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with subcutaneous risankizumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following ('i" and "ii"):
        i. Subcutaneous risankizumab will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific criteria are met
        ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")
            I. The member's age is within FDA labeling for the requested indication for subcutaneous risankizumab
            II. The prescriber has provided information in support of using subcutaneous risankizumab for the member's age for the requested indication
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for PS, gastroenterologist for CD, rheumatologist for PsA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to subcutaneous risankizumab
4. Member has been tested for latent tuberculosis (TB) **AND**, if positive, the member has begun therapy for latent TB
5. Member will **NOT** be using subcutaneous risankizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", or "c"):
    a. The dosage does not exceed:
        - Plaque psoriasis and psoriatic arthritis
            - Loading dose - 150 mg at weeks 0 and 4
            - Maintenance dose - 150 mg every 12 weeks (84 days), starting 12 weeks after week 4 (i.e., on week 16)
                - QL: 150 mg/mL auto-injector - 1 pen/84 days
                - QL: 150 mg/mL prefilled syringe - 1 syringe/84 days
                - QL: 2 x 75 mg/0.83 mL syringe, kit - 1 kit/84 days
        - Crohn's disease (CD)
            - Loading dose – Induction is given by IV infusion only. The IV dosage is 600 mg every 4 weeks for 3 total doses (i.e., weeks 0, 4, and 8)

- Maintenance dose - 360 mg subcutaneously every 8 weeks (56 days), starting 4 weeks after the last IV dose (i.e., on week 12)
  - QL: 180 mg/1.2 mL prefilled cartridge with on-body injector – 1 cartridge/56 days
  - QL: 360 mg/2.4 mL prefilled cartridge with on-body injector – 1 cartridge/56 days

b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required)

Approval duration: For CD – Approved for 9 months [this equals a 1-year total treatment duration with IV loading doses]. Other indications - Loading dose (doses on week 0 and 4) for 4 months, then maintenance dose for 8 additional months [12 months for total duration of approval].

Table 2

Diagnosis	Criteria
Moderate to severe plaque psoriasis (PS)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3 months **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** 4. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR**

	5. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS
Active psoriatic arthritis (PsA)	**ONE** of the following: 1. The member has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3 months **OR** 2. The member has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA
Moderately to severely active Crohn's disease (CD)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3 months **OR**

	2. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of CD **OR** 3. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of CD **OR** 4. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **OR** 5. The member has severe disease and/or risk factors for disease complications for which initial treatment with risankizumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of subcutaneous risankizumab (Skyrizi) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for subcutaneous risankizumab has been previously approved by Florida Blue
2. Member has had clinical benefit with subcutaneous risankizumab therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for PS, gastroenterologist for CD, rheumatologist for PsA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to subcutaneous risankizumab
5. Member will **NOT** be using subcutaneous risankizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", or "c"):
    a. The dosage does not exceed the following:
        - Plaque psoriasis and psoriatic arthritis - 150 mg every 12 weeks (84 days)
            - QL: 150 mg/mL auto-injector - 1 pen/84 days
            - QL: 150 mg/mL prefilled syringe - 1 syringe/84 days

- QL: 2 x 75 mg/0.83 mL syringe, kit - 1 kit/84 days

- CD - 360 mg every 8 weeks (56 days)
  - QL: 180 mg/1.2 mL prefilled cartridge with on-body injector – 1 cartridge/56 days
  - QL: 360 mg/2.4 mL prefilled cartridge with on-body injector – 1 cartridge/56 days

b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication (submitted copy required; e.g., clinical trials, phase III studies, guidelines required)

Approval duration: 12 months

INTRAVENOUS SKYRIZI (MEDICAL BENEFIT)

Initiation of intravenous (IV) risankizumab (Skyrizi) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "6"):

1. Intravenous risankizumab will be used for the treatment of an indication listed in Table 3, and **ALL** of the indication-specific and maximum-allowable dose criteria are met
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., gastroenterologist for CD) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to IV risankizumab
4. Member has been tested for latent tuberculosis (TB) **AND**, if positive, the member has begun therapy for latent TB
5. Member will **NOT** be using IV risankizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. For CD indication only - member has not received a previous dose of risankizumab (IV or SC) in the past 12 months, **UNLESS** the member is completing the second and/or third dose(s) of the initial 3 IV doses for induction

Approval duration: CD - 3 months (to allow 3 total IV doses). Other indications - Up to 12 months.

Table 3

Indication	Criteria	Max Allowable Dosage
Moderately to severely active Crohn's disease (CD)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD for at least 3 months **OR** 2. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of CD **OR** 3. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of CD **OR** 4. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **OR** 5. The member has severe disease and/or risk factors for disease complications for which initial treatment with risankizumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors	• 600 mg IV every 4 weeks for a total of 3 doses (i.e., Week 0, Week 4, and Week 8) • Maintenance therapy with subcutaneous risankizumab is started 4 weeks after the last IV dose (i.e., Week 12)
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence,	Maximum dose supported by the FDA labeled indication or maximum dose supported in

	AHFS, or NCCN compendium recommended use 1 or 2a	DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2A

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Risankizumab is indicated for (1) the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, (2) the treatment of active psoriatic arthritis in adults, and (3) the treatment of moderately to severely active Crohn's disease in adults.
    - Plaque psoriasis and psoriatic arthritis - The recommended dose is 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. For the indication of psoriatic arthritis, the labeling states that risankizumab may be administered alone or in combination with non-biologic DMARDs. When using 75 mg/0.83 mL prefilled syringes, for a 150 mg dose, two 75 mg prefilled syringes are required. Inject one prefilled syringe after the other in different anatomic locations (such as thighs or abdomen). Do not inject into areas where the skin is tender, bruised, erythematous, indurated or affected by psoriasis. Administration in the upper, outer arm may only be performed by a healthcare professional or caregiver.
    - Crohn's disease - The recommended induction dosage is 600 mg administered by IV infusion over a period of at least one hour at Week 0, Week 4, and Week 8. The recommended maintenance dosage is 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dosage needed to maintain therapeutic response. Use the on-body injector to administer the 180 mg/1.2 mL or 360 mg/2.4 mL prefilled cartridge subcutaneously on thigh or abdomen. Do not inject into areas where the skin is tender, bruised, erythematous, indurated or affected by any lesions. Obtain liver enzymes and bilirubin levels prior to initiating treatment. Refer to the product labeling for more information regarding preparation and administration.

Dose Adjustments

- Renal impairment - specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed
- Hepatic impairment - specific guidelines for dosage adjustments in hepatic impairment are not available; it appears that no dosage adjustments are needed.

Drug Availability

- Intravenous Infusion
    - Carton with one 600 mg/10 mL (60 mg/mL) single-dose vial

- Subcutaneous Injection
  - Carton with one 150 mg/mL singe-dose prefilled syringe
  - Carton with one 150 mg/mL singe-dose pen
  - Carton with two 75 mg/0.83 mL singe-dose prefilled syringes (150 mg total for both syringes)
  - Kit with 180 mg/1.2 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector
  - Kit with 360 mg/2.4 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector
- Store in a refrigerator at 2°C to 8°C (36°F to 46° F). Do not freeze. Do not shake. Keep in the outer carton to protect from light. Not made with natural rubber latex.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Patients with a history of serious hypersensitivity reaction to risankizumab or any of the excipients

Precautions/Warnings

- **Hypersensitivity Reactions**: Serious hypersensitivity reactions, including anaphylaxis, have been reported with use. If a serious hypersensitivity reaction occurs, discontinue and initiate appropriate therapy immediately.
- **Infections**: may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer until the infection resolves.
- **Tuberculosis (TB)**: Evaluate for TB prior to initiating treatment.
- **Hepatotoxicity in Treatment of Crohn's Disease**: Drug-induced liver injury during induction has been reported. Monitor liver enzymes and bilirubin levels at baseline and, during induction, up to at least 12 weeks of treatment. Monitor thereafter according to routine patient management.
- **Administration of Vaccines**: Avoid use of live vaccines in patients.

BILLING/CODING INFORMATION:

HCPCS Coding

J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3590	Unclassified biologics (for the subcutaneous formulation only)

ICD-10 Diagnosis Codes That Support Medical Necessity of Intravenous Infusion (J2327):

K50.00 – K50.919	Crohn's disease [regional enteritis]

ICD-10 Diagnosis Codes That Support Medical Necessity of Subcutaneous Injection (J3590):

K50.00 – K50.919	Crohn's disease [regional enteritis]
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

DEFINITIONS:

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

Plaque psoriasis: It is the most common form of psoriasis. It affects 80 to 90% of people with psoriasis. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin. These areas are called plaques.

Psoriatic arthritis: joint inflammation that occurs in about 5% to 10% of people with psoriasis (a common skin disorder). It is a severe form of arthritis accompanied by inflammation, psoriasis of the skin or nails, and a negative test for rheumatoid factor. Enthesitis refers to inflammation of entheses, the site where ligaments or tendons insert into the bones. It is a distinctive feature of PsA and does not occur with other forms of arthritis. Common locations for enthesitis include the bottoms of the feet, the Achilles' tendons, and the places where ligaments attach to the ribs, spine, and pelvis.

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67
Adalimumab (Humira), 09-J0000-46
Apremilast (Otezla) Tablet, 09-J2000-19
Brodalumab (Siliq) Injection, 09-J2000-74
Certolizumab Pegol (Cimzia), 09-J0000-77
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87
Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), and infliximab-abda (Renflexis)], 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Natalizumab (Tysabri) Injection, 09-J0000-73
Psoralens with Ultraviolet A (PUVA), 09-10000-16
Secukinumab (Cosentyx), 09-J2000-30
Tildrakizumab-asmn (Ilumya), 09-J3000-04
Tofacitinib (Xeljanz, Xeljanz XR) Tablets, 09-J1000-86
Ustekinumab (Stelara), 09-J1000-16
Vedolizumab (Entyvio) Injection, 09-J2000-18

OTHER:

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy

Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)

Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Omvoh (mirikizumab-mrkz)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi Aria (golimumab)
Skyrizi (risankizumab-rzaa)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Wezlana (ustekinumab-auub)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zymfentra (infliximab-dyyb)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/08/23.

GUIDELINE UPDATE INFORMATION:

09/01/19	New Medical Coverage Guideline.
01/01/20	Revision to guideline consisting of updating the position statement “Note” due to changes in preferred products.
07/01/20	Revision to guideline consisting of updating the description and position statement.
01/01/21	Review and revision to guideline consisting of updating the position statement and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.

07/15/21	Revision to guideline consisting of updating the position statement, dosage/administration, other section, and references.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the position statement, other section, and references.
02/15/21	Update to Table 1 in Position Statement.
03/15/22	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, other section, definitions, related guidelines, and references based on the new FDA-approved indication for active psoriatic arthritis in adults.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, related guidelines, and references based on the new FDA-approved indication for CD.
01/01/23	Review and revision to guideline consisting of updating the description section, position statement, dosage/administration, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination. A new 180 mg on-body injector dosage for CD was released. Added HCPCS code J2327.
04/15/23	Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the position statement, other section, and references. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.