Skyrizi® (Risankizumab-Rzaa)

Policy Number: 2024D0116E
Effective Date: October 1, 2024

➲ Instructions for Use

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Related Commercial Policies

- Provider Administered Drugs – Site of Care

Coverage Rationale

This policy refers to Skyrizi (risankizumab-rzaa) injection for intravenous use. Skyrizi (risankizumab-rzaa) for self-administered subcutaneous injection is obtained under the pharmacy benefit.

Crohn's Disease (CD)

Skyrizi is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met:

- Diagnosis of moderately to severely active Crohn's disease; **and**
- Skyrizi is to be administered as three intravenous induction doses; **and**
- Skyrizi induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and**
- Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab)]; **and**
- Authorization will be issued for 3 induction doses

Skyrizi is medically necessary for the treatment of Crohn's disease (CD) when all of the following criteria are met:

- Diagnosis of moderately to severely active Crohn's disease; **and**
- One of the following:
  - History of failure to **one** of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
    - Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
    - 6-mercaptopurine (Purinethol)
    - Azathioprine (Imuran)
    - Methotrexate (Rheumatrex, Trexall)

    or
  - Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Stelara (ustekinumb), Cimzia (certolizumab pegol), Rinvoq (upadacitinib)]

  and
- Skyrizi is to be administered as three intravenous induction doses; **and**
- Skyrizi induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and**
- Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab)]; **and**
- Prescribed by or in consultation with a gastroenterologist; **and**

- Authorization will be issued for 3 induction doses

Ulcerative Colitis (UC)

Skyrizi is proven for the treatment of ulcerative colitis when all of the following criteria are met:

- Diagnosis of moderately to severely active ulcerative colitis; **and**
- Skyrizi is to be administered as three intravenous induction doses; **and**
- Skyrizi induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for UC; **and**
  Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Omvoh (mirikizumab-mrkz)]; **and**
- Authorization will be issued for 3 induction doses

Skyrizi is medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:

- Diagnosis of moderately to severely active ulcerative colitis; **and**
- **One** of the following:
  - Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); **or**
  - Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

  and
- Skyrizi is to be administered as three intravenous induction doses; **and**
- Skyrizi induction dosing is in accordance with the U.S FDA labeled dosing for UC; **and**
- Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Omvoh (mirikizumab-mrkz)]; **and**
- Prescribed by or in consultation with a gastroenterologist; **and**
- Authorization will be issued for 3 induction doses

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg

Diagnosis Code	Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess

Diagnosis Code	Description
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) recto sigmoiditis without complications
K51.311	Ulcerative (chronic) recto sigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) recto sigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) recto sigmoiditis with fistula
K51.314	Ulcerative (chronic) recto sigmoiditis with abscess
K51.318	Ulcerative (chronic) recto sigmoiditis with other complication
K51.319	Ulcerative (chronic) recto sigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications

Diagnosis Code	Description
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis

Background

Skyrizi is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Skyrizi inhibits the release of pro-inflammatory cytokines and chemokines.

Clinical Evidence

Proven

Crohn's Disease

ADVANCE and MOTIVATE were randomized, double-masked, placebo-controlled, phase 3 induction studies. Eligible patients aged 16–80 years with moderately to severely active Crohn's disease, previously showing intolerance or inadequate response to one or more approved biologics or conventional therapy (ADVANCE) or to biologics (MOTIVATE), were randomly assigned to receive a single dose of intravenous risankizumab (600 mg or 1200 mg) or placebo (2:2:1 in ADVANCE, 1:1:1 in MOTIVATE) at weeks 0, 4, and 8. We used interactive response technology for random assignment, with stratification by number of previous failed biologics, corticosteroid use at baseline, and Simple Endoscopic Score for Crohn's disease (SES-CD). All patients and study personnel (excluding pharmacists who prepared intravenous solutions) were masked to treatment allocation throughout the study. Coprimary endpoints were clinical remission (defined by Crohn's disease activity index [CDAI] or patient-reported outcome criteria [average daily stool frequency and abdominal pain score]) and endoscopic response at week 12. The intention-to-treat population (all eligible patients who received at least one dose of study drug in the 12-week induction period) was analyzed for efficacy outcomes. Safety was assessed in all patients who received at least one dose of study drug.

Participants were enrolled between May 10, 2017, and Aug 24, 2020 (ADVANCE trial), and Dec 18, 2017 and Sept 9, 2020 (MOTIVATE trial). In ADVANCE, 931 patients were assigned to either risankizumab 600 mg (n = 373), risankizumab 1200 mg (n = 372), or placebo (n = 186). In MOTIVATE, 618 patients were assigned to risankizumab 600 mg (n = 206), risankizumab 1200 mg (n = 205), or placebo (n = 207). The primary analysis population comprised 850 participants in ADVANCE and 569 participants in MOTIVATE. All coprimary endpoints at week 12 were met in both trials with both doses

of risankizumab (p values ≤ 0·0001). In ADVANCE, CDAI clinical remission rate was 45% (adjusted difference 21%, 95% CI 12–29; 152/336) with risankizumab 600 mg and 42% (17%, 8–25; 141/339) with risankizumab 1200 mg versus 25% (43/175) with placebo; stool frequency and abdominal pain score clinical remission rate was 43% (22%, 14–30; 146/336) with risankizumab 600 mg and 41% (19%, 11–27; 139/339) with risankizumab 1200 mg versus 22% (38/175) with placebo; and endoscopic response rate was 40% (28%, 21–35; 135/336) with risankizumab 600 mg and 32% (20%, 14–27; 109/339) with risankizumab 1200 mg versus 12% (21/175) with placebo. In MOTIVATE, CDAI clinical remission rate was 42% (22%, 13–31; 80/191) with risankizumab 600 mg and 40% (21%, 12–29; 77/191) with risankizumab 1200 mg versus 20% (37/187) with placebo; stool frequency and abdominal pain score clinical remission rate was 35% (15%, 6–24; 66/191) with risankizumab 600 mg and 40% (20%, 12–29; 76/191) with risankizumab 1200 mg versus 19% (36/187) with placebo; and endoscopic response rate was 29% (18%, 10–25; 55/191) with risankizumab 600 mg and 34% (23%, 15–31; 65/191) with risankizumab 1200 mg versus 11% (21/187) with placebo. The overall incidence of treatment-emergent adverse events was similar among the treatment groups in both trials. Three deaths occurred during induction (two in the placebo group [ADVANCE] and one in the risankizumab 1200 mg group [MOTIVATE]). The death in the risankizumab-treated patient was deemed unrelated to the study drug.

Risankizumab was effective and well tolerated as induction therapy in patients with moderately to severely active Crohn's disease.

FORTIFY is a phase 3, multicenter, randomized, double-blind, placebo-controlled, maintenance withdrawal study across 273 clinical centers in 44 countries across North and South America, Europe, Oceania, Africa, and the Asia-Pacific region that enrolled participants with clinical response to risankizumab in the ADVANCE or MOTIVATE induction studies. Patients in ADVANCE or MOTIVATE were aged 16–80 years with moderately to severely active Crohn's disease. Patients in the FORTIFY sub study 1 were randomly assigned again (1:1:1) to receive either subcutaneous risankizumab 180 mg, subcutaneous risankizumab 360 mg, or withdrawal from risankizumab to receive subcutaneous placebo (herein referred to as withdrawal [subcutaneous placebo]). Treatment was given every 8 weeks. Patients were stratified by induction dose, post-induction endoscopic response, and clinical remission status. Patients, investigators, and study personnel were masked to treatment assignments. Week 52 co-primary endpoints were clinical remission (Crohn's disease activity index [CDAI] in the US protocol, or stool frequency and abdominal pain score in the non-US protocol) and endoscopic response in patients who received at least one dose of study drug during the 52-week maintenance period. Safety was assessed in patients receiving at least one dose of study medication.

712 patients were initially assessed and, between April 9, 2018, and April 24, 2020, 542 patients were randomly assigned to either the risankizumab 180 mg group (n = 179), the risankizumab 360 mg group (n = 179), or the placebo group (n = 184). Greater clinical remission and endoscopic response rates were reached with 360 mg risankizumab versus placebo (CDAI clinical remission was reached in 74 (52%) of 141 patients *vs* 67 (41%) of 164 patients, adjusted difference 15% [95% CI 5–24]; stool frequency and abdominal pain score clinical remission was reached in 73 (52%) of 141 *vs* 65 (40%) of 164, adjusted difference 15% [5–25]; endoscopic response 66 (47%) of 141 patients *vs* 36 (22%) of 164 patients, adjusted difference 28% [19–37]). Higher rates of CDAI clinical remission and endoscopic response (but not stool frequency and abdominal pain score clinical remission [p = 0·124]) were also reached with risankizumab 180 mg versus withdrawal (subcutaneous placebo; CDAI clinical remission reached in 87 [55%] of 157 patients, adjusted difference 15% [95% CI 5–24]; endoscopic response 74 [47%] of 157, adjusted difference 26% [17–35]). Results for more stringent endoscopic and composite endpoints and inflammatory biomarkers were consistent with a dose–response relationship. Maintenance treatment was well tolerated. Adverse event rates were similar among groups, and the most frequently reported adverse events in all treatment groups were worsening Crohn's disease, arthralgia, and headache.

Subcutaneous risankizumab is a safe and efficacious treatment for maintenance of remission in patients with moderately to severely active Crohn's disease and offers a new therapeutic option for a broad range of patients by meeting endpoints that might change the future course of disease.

Ulcerative Colitis

In the 12-week induction study, INSPIRE, 966 subjects with moderately to severely active ulcerative colitis were randomized and received risankizumab 1,200 mg or placebo as an intravenous infusion at Week 0, Week 4, and Week 8. Disease activity was assessed by the modified Mayo score (mMS), a 3-component Mayo score (0-9) which consists of the following subscores (0 to 3 for each subscore): stool frequency (SFS), rectal bleeding (RBS), and findings on centrally read endoscopy score (ES). An ES of 2 was defined by marked erythema, lack of vascular pattern, any friability, and/or erosions; an ES of 3 was defined by spontaneous bleeding and ulceration. Enrolled subjects had a mMS between 5 and 9, with an ES of 2 or 3. Subjects with inadequate response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators, biologics, Janus Kinase inhibitors (JAKi), and/or sphingosine-1-phospate receptor modulators (S1PRM) were enrolled.

At baseline in INSPIRE, the median mMS was 7; 37% had severely active disease (mMS > 7); 69% had an ES of 3. In INSPIRE, 52% (499/966) of subjects had failed (inadequate response or intolerance) treatment with one or more biologics, JAKi or S1PRM. Of these 499 subjects, 484 (97%) failed biologics and 90 (18%) failed JAK inhibitors. Enrolled subjects were permitted to use a stable dose of oral corticosteroids (up to 20 mg/day prednisone or equivalent), immunomodulators, and aminosalicylates. At baseline, 36% of subjects were receiving corticosteroids, 16% of subjects were receiving immunomodulators (including azathioprine, 6- mercaptopurine, methotrexate), and 73% of subjects were receiving aminosalicylates in INSPIRE.

In INSPIRE, the primary endpoint was clinical remission defined using the mMS at Week 12 (total population clinical remission was 24% with risankizumab vs. 8% with placebo). Key secondary endpoints included clinical response, endoscopic improvement, and histologic endoscopic mucosal improvement (total population clinical response was 65% on risankizumab vs. 36% on placebo, endoscopic improvement was 36% on risankizumab vs. 12% on placebo, and histiologic endoscopic mucosal improvement was 24% on risankizumab vs. 7% on placebo).

The maintenance study, COMMAND evaluated 547 subjects who received one of three SKYRIZI induction regimens, including the 1,200 mg regimen, for 12 weeks in Studies UC-1 or UC-3 and demonstrated clinical response per mMS after 12 weeks. Subjects were randomized to receive a maintenance regimen of subcutaneous (SC) SKYRIZI 180 mg or SKYRIZI 360 mg or placebo at Week 12 and every 8 weeks thereafter for up to an additional 52 weeks.

In COMMAND, 75% (411/547) of subjects had failed (inadequate response or intolerance) treatment with one or more biologics, JAKi, or S1PRM. Of these 411 subjects, 407 (99%) failed biologics and 78 (19%) failed JAK inhibitors.

The primary endpoint in COMMAND was clinical remission using mMS at Week 52 (total population clinical remission was 45% with risankizumab vs. 26% with placebo). Key secondary endpoints included corticosteroid-free clinical remission, endoscopic improvement, and histologic endoscopic mucosal improvement (total population corticosteroid-free clinical remission was 45% on risankizumab vs. 26% on placebo, endoscopic improvement was 51% on risankizumab vs. 31% on placebo, and histiologic endoscopic mucosal improvement was 43% on risankizumab vs. 24% on placebo).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Skyrizi is an interleukin-23 antagonist indicated for the treatment of:
- Moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis in adults
- Moderately to severely active Crohn's disease in adults
- Moderately to severely active ulcerative colitis in adults

References

1. D'Haens G, Panaccione R, Baert F, et al. Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials. *Lancet*. 2022;399(10340):2015-2030.
2. Ferrante M, Panaccione R, Baert F, et al. Risankizumab as maintenance therapy for moderately to severely active Crohn's disease: results from the multicenter, randomised, double-blind, placebo-controlled, withdrawal phase 3 FORTIFY maintenance trial.*Lancet*. 2022;399(10340):2031-2046.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018; 113:481-517.
4. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
5. Risankizumab Induction Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Efficacy and Safety in the Randomized Phase 3 INSPIRE Study. Gastroenterol Hepatol (N Y). 2023 Dec;19(12 Suppl 9):9-10.

Policy History/Revision Information

Date	Summary of Changes
10/01/2024	**Coverage Rationale** ***Ulcerative Colitis (UC)*** • Added language to indicate:

Date	Summary of Changes
	○ Skyrizi is proven for the treatment of UC when all of the following criteria are met: ▪ Diagnosis of moderately to severely active UC ▪ Skyrizi is to be administered as three intravenous induction doses ▪ Skyrizi induction dosing is in accordance with the U.S. FDA labeled dosing for UC ▪ Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Omvoh (mirikizumab-mrkz)] ▪ Authorization will be issued for 3 induction doses ○ Skyrizi is medically necessary for the treatment of UC when all of the following criteria are met: ▪ Diagnosis of moderately to severely active UC ▪ One of the following: – Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine) – Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of UC [e.g., adalimumab, Simponi (golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)] ▪ Skyrizi is to be administered as three intravenous induction doses ▪ Skyrizi induction dosing is in accordance with the U.S. FDA labeled dosing for UC ▪ Patient is not receiving Skyrizi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Omvoh (mirikizumab-mrkz)] ▪ Prescribed by or in consultation with a gastroenterologist ▪ Authorization will be issued for 3 induction doses **Applicable Codes** • Added ICD-10 diagnosis codes K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918, K51.919, and K52.1 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2023D00116D

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.