To: **Jai Medical Providers**
From: **MC-Rx**
Date: **July 31, 2024**
Subject: **Formulary Update August 2024**

Effective 8/1/2024, the following products will be added to the formulary:

- Simlandi (Humira biosimilar adalimumab-ryvk) – Biosimilar was added to the drug list with the same prior authorization (PA) criteria as the other Humira biosimilars on the formulary (Hadlima and adalimumab-adaz) – Humira biosimilar criteria is listed later in this notice
- Rinvoq LQ oral solution was added to the drug list with a PA requirement. Rinvoq PA criteria were updated to reflect changes in pediatric indication due to new formulation.
- Valacyclovir Tablet was added to drug list with a PA requirement (Criteria listed later in this notice).

Effective 8/1/2024, the following changes will be made to medications on the formulary:

- Jardiance and generic Farxiga will move from PA Requirement to Step Therapy
  Step Therapy Criteria: 60 days in previous 180 days of Metformin, sulfonylurea, pioglitazone, ACE, ARB, ARNI, or Beta Blocker
  (Any requests for brand Farxiga would require a prior authorization request for brand medical necessity.)

Effective 8/1/2024, the following medications will have updates made to their criteria:

- Rinvoq/Rinvoq LQ: Updates were made to reflect the differences in indication due to the new formulation
- Xolair: Updates were made to reflect the new indication
- Gender Affirming Care Criteria references for Nafarelin, Testosterone, and Leuprolide - The following language will be listed in the criteria:
  For all requests for gender affirming care, please refer to the Gender-Affirming Treatment Services Under the Maryland Medicaid Program document. Please ensure that all necessary documentation required under the criteria is included to show consent for treatment and medical necessity (documentation requirements may vary depending on patient age, type of treatment requested, and specialty of requesting provider).

Prior Authorization Criteria:

PA Description	**Valacyclovir hydrochloride tablet**
Covered Uses	All FDA approved indications: (a) Adult Patients a. Treatment of cold sores (herpes labialis). (ICD 10 CM B00.1) b. Genital Herpes (ICD 10 CM A60. 0)

PA Description	Valacyclovir hydrochloride tablet
	i. Treatment in immunocompetent patients (initial or recurrent episode) ii. Suppression in immunocompetent or HIV-1–infected patients iii. Reduction of transmission of genital herpes in immunocompetent adults. c. Treatment of herpes zoster (shingles) in immunocompetent adults. (ICD 10 CM B02) (b) Pediatric Patients a. Treatment of cold sores (herpes labialis) in pediatric patients aged 12 years or older. (ICD 10 CM B00.1) b. Treatment of chickenpox in immunocompetent pediatric patients aged 2 to less than 18 years. (ICD 10 CM B01) Limitations of Use: The efficacy and safety of VALACYCLOVIR have not been established in immunocompromised patients other than for the suppression of genital herpes in HIV-1–infected patients.
Exclusion Criteria	(a) Hypersensitivity to valacyclovir (e.g., anaphylaxis), acyclovir, or any component of the formulation.
Required Medical Information	(a) Adult Patients a. For management of cold sores (herpes labialis), Genital Herpes, or herpes zoster (shingles) i. Document trial, failure, or contraindication to acyclovir or document rationale supporting acyclovir is not inappropriate. (b) Pediatric Patients a. Treatment of cold sores (herpes labialis) in pediatric patients aged greater than or equal to 12 years. (ICD 10 CM B00.1) i. Document trial, failure, or contraindication to acyclovir or document rationale supporting acyclovir is not inappropriate b. Treatment of chickenpox in immunocompetent pediatric patients aged 2 to less than 18 years. (ICD 10 CM B01) i. Document trial, failure, or contraindication to acyclovir or document rationale supporting acyclovir is not inappropriate
Age Restriction	(a) Treatment of cold sores (herpes labialis) in pediatric patients aged greater than or equal to 12 years. (b) Treatment of chickenpox in immunocompetent pediatric patients aged 2 to less than 18 years.
Coverage Duration	(a) Per indication
Other Criteria	(a) Refer to package insert information for dosage and administration. (b) Guidelines suggest **not administering antiviral therapy for healthy children ≤12 years.** Varicella is typically a self-limited disease in this population. Although acyclovir may modestly reduce the duration and severity of symptoms, these benefits must be weighed against the adverse effects (including rare but potentially serious adverse effects), cost, and potential transmission of infection during the office visit to obtain the prescription. https://www.cdc.gov/chickenpox/hcp/clinical-overview/

PA Description	Upadacitinib (Rinvoq tablet/Rinvoq LQ)
Covered Uses	All FDA approved indications: (a) **Rinvoq:** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with rheumatoid arthritis (RA). (b) **Rinvoq/Rinvoq LQ**: Treatment of adult and pediatric patients 2 years of age and older, who have had an inadequate response or intolerance to one or more TNF blockers, with active psoriatic arthritis (PsA). (c) **Rinvoq:** Treatment of pediatric patients 12 years and older, who have had an inadequate response or intolerance to other systemic drug products, including biologics, with active atopic dermatitis (AD). (d) **Rinvoq:** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active ulcerative colitis (UC). (e) **Rinvoq:** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active ankylosing spondylitis (AS). (f) **Rinvoq:** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active non-radiographic axial spondyloarthritis (nr-axSpA). (g) **Rinvoq/Rinvoq LQ**: For the treatment of patients 2 years of age and older with active **polyarticular juvenile idiopathic arthritis** (PJIA) who have had an inadequate response or intolerance to one or more TNF blockers.
Exclusion Criteria	(a) Combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine
Required Medical Information	(a) First Prescription and every 12 months: i. The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment. ii. The patient had a NEGATIVE hepatitis B and C viral screening (b) For adult patients with RA i. Previous treatment, or intolerance of Enbrel for more than sixty (60) days; and ii. Previous treatment, or intolerance of formulary Humira biosimilar for more than sixty (60) days (c) For adult patients with PsA i. previous treatment, or intolerance of Enbrel for more than sixty (60) days; and ii. Previous treatment, or intolerance of formulary Humira biosimilar for more than sixty (60) days; and iii. Previous treatment, or intolerance of Taltz for more than sixty (60) days (d) For pediatric patients 2 years of age and older with PsA i. Previous treatment, or intolerance of Enbrel for more than sixty (60) days; and

<table>
<tr><td></td><td>ii. Previous treatment, or intolerance of formulary Humira biosimilar for more than sixty (60) days;
(e) For patients 2 years of age and older with PJIA
i. Previous treatment, or intolerance of Enbrel for more than sixty (60) days; and
ii. Previous treatment, or intolerance of formulary Humira biosimilar for more than sixty (60) days

(f) For patients 12 years and older with AD
i. Previous treatment, or intolerance of Dupixent for more than sixty (60) days
(g) For adult patients with UC
i. Previous treatment, or intolerance of formulary Humira biosimilar for more than sixty (60) days
(h) For adult patients with AS and nr-asSpA
i. Previous treatment, or intolerance of Taltz for more than sixty (60) days</td></tr>
<tr><td>Age Restriction</td><td>(a) Psoriatic arthritis or polyarticular juvenile idiopathic arthritis: for patients 2 years of age or older
(b) Atopic dermatitis (AD) for patients 12 years and older
(c) Polyarticular juvenile idiopathic arthritis (PJIA) For patients 2 years of age and older</td></tr>
<tr><td>Coverage Duration</td><td>(a) One (1) Year</td></tr>
<tr><td>Other Criteria</td><td>Table. RINVOQ/RINVOQ LQ Dosage for Pediatric Patients 2 Years to Less Than 18 Years of Age with Psoriatic Arthritis and Patients 2 years and older with pJIA
<table><tr><th>Patient Weight</th><th>RINVOQ LQ</th><th>RINVOQ</th></tr><tr><td>10 kg to less than 20 kg</td><td>3 mg (3 mL oral solution) twice daily</td><td>Not recommended</td></tr><tr><td>20 kg to less than 30 kg</td><td>4 mg (4 mL oral solution) twice daily</td><td>Not recommended</td></tr><tr><td>30 kg and greater</td><td>6 mg (6 mL oral solution) twice daily</td><td>15 mg (one 15 mg tablet) once daily</td></tr></table></td></tr>
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PA Description	OMALIZUMAB (XOLAIR®)
Covered Uses	(a) Treatment of moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. ICD-10-CM J45.40, ICD-10-CM J45.50 (b) Treatment of adult patients, as an add-on maintenance treatment, chronic rhinosinusitis with nasal polyposis (CRSwNP). (ICD-10-CM J333.9) (c) Treatment of adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment with chronic spontaneous urticaria (CSU). (ICD-10-CM L50.1) (d) IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur

PA Description	OMALIZUMAB (XOLAIR®)
	with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance (ICD-10-CM Z91.01, Z91.02, Z91.18, T78.0)
Required Medical Information	**(a) For pediatric patients 6 years and older with asthma** i. Documentation of baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL ii. Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen iii. Previous treatment, or intolerance of, with two (2) or more inhaled medium to high dose LABA+ICS for more than sixty (60) days; and iv. Patients must be reevaluated after 6 months **(b) For adult patients with asthma** i. Documentation of baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL ii. Documentation of positive skin test or in vitro reactivity to a perennial aeroallergen iii. Previous treatment, or intolerance of, with LAMA+LABA+ICS for more than sixty (60) days; and iv. Patients must be reevaluated after 6 months **(c) For adult patients with CRSwNP** i. Previous treatment, or intolerance of, with two (2) or more intranasal corticosteroid for more than ninety (90) days; and ii. Previous treatment, or intolerance of, with oral corticosteroid **(d) For pediatric patients 12 years and older with CSU** Previous treatment with two (2) H1-antihistamines for more than sixty (60) days within the past ninety (90) days **(a) IgE-mediated food allergy:** i. First Prescription Only: (1) Documentation of patient's diagnosis (2) Documentation of baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL (3) Documentation of patient's weight

PA Description	ADALIMUMAB-BWWD (HADLIMA), ADALIMUMAB-ADAZ (HYRIMOZ UNBRANDED), ADALIMUMAB-RYVK (SIMLANDI)
Covered Uses	All FDA approved indications: (a) Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. (ICD10-CM M06.9, ICD-10-CM M05, ICD-10-CM M05.9). (b) Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. (ICD10-CM M08.00).

	(c) Psoriatic Arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. (ICD10-CM L40.59, L40.50). (d) Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS. (ICD10-CM M45.9). (e) Crohn's Disease (CD): Treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. ICD-10-CM K50.0 - K50.90 (f) Ulcerative Colitis (UC Treatment of moderately to severely active ulcerative colitis in adult patients. (ICD10-CM K51.90). (g) Plaque Psoriasis (PsO): The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. (ICD10-CM L40.0). (h) Hidradenitis Suppurativa (HS): The treatment of moderate to severe hidradenitis suppurativa in adult patients. (ICD10-CM L73.2). (i) Uveitis (UV): The treatment of non-infectious intermediate, posterior and panuveitis in adult patients. (ICD10-CM: H44.139 o ICD10-CM: H44.11)
Exclusion Criteria	(a) Combination therapy with other biologic agent(s)
Required Medical Information	(a) **First Prescription and every 12 months:** a. The patient had a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to therapy; **and** b. The patient does not have a clinically important active infection (b) **Additional Criteria for RA, JIA, and PsA**: For the **First Prescription Only** a. The patient has failed or is intolerant to one formulary NSAID and b. The patient has failed or is intolerant to one formulary DMARD (c) **Additional Criteria for AS:** For the **First Prescription Only** a. Physician documents that patient failed treatment with at least two NSAIDS for at least three months, except if NSAIDs are contraindicated or if patient has presented toxicity or intolerance. (d) **Additional Criteria for CD and UC:** For the **First Prescription Only** a. The patient has failed or is intolerant to infliximab; or b. The patient has failed or is intolerant to mesalamine or sulfasalazine; and c. The patient has failed or is intolerant to corticosteroids; and d. The patient has failed or is intolerant to an immunomodulator (e.g., methotrexate,6- mercaptopurine or azathioprine) (e) **Additional Criteria for Ps** For the **First Prescription Only** a. Document that the patient has an incomplete response or intolerance or contraindicated to one appropriate systemic agent (ex: MTX, cyclosporine, acitretin) or phototherapy or biologic agents. (f) **Additional Criteria for Hs** For the **First Prescription Only** a. Documentation of evidence failure with the previous treatment including antibiotics, hormonal therapies or oral retinoid at least for 90 days.

Age Restriction	(a) For Polyarticular juvenile idiopathic arthritis: patients 2 years of age or older (b) Crohn's disease: patients 6 years of age or older.
Coverage Duration	(a) One (1) Year
Other Criteria	(a) Follow package insert instructions for dose modification. (b) Patients treated with ADALIMUMAB are at increased risk of developing serious infections that may lead to hospitalization or death. The physician should be aware and follow up the patient's conditions prior and during treatment. (c) **Differences: Humira and biosimilar indications** • **UC**: Humira has pediatric indication for UC: 5 years and older; Simlandi/ Hadlima/Adalimumab-adaz only approved for adults • **Hidradenitis Suppurativa** (HS): Humira approved in patients 12 years of age and older; Simlandi/Hadlima/ Adalimumab-adaz only approved for adults • **Uveitis** (UV): Humira approved for pediatric patients 2 years of age and older; Simlandi/Hadlima/ Adalimumab-adaz only approved for adults • All other indications are the same between biosimilars and Humira (reference product).

Providers can contact MC-Rx's Prior-Authorization Department at 800-555-8513 for assistance with PA requests or questions regarding clinical guidelines. Our PA Department is available Monday through Friday from 8:30 am-5:30 pm EST. For assistance with PA requests during non-business hours please contact our 24-hour customer service department at 800-213-5640.