To: **Jai Medical Providers**
From: **MC-Rx**
Date: **July 1, 2025**
Subject: **Formulary Update – July 2025**

Effective Immediately, the following medications will be added to the formulary with prior authorization required and $1 copay status:

- Yesintek (Ustekinumab-kfce, an interchangeable Stelara biosimilar) – Criteria included below
- Eligard (leuprolide) – Criteria included below

Medication	**USTENKINUMAB-KFCE (YESINTEK PREFILLED SYRINGE 45MG/0.5ML, PREFILLED SYRINGE 90MG/ML)**
Covered Uses	All FDA approved indications: • Indicated for the treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. • Indicated for the treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis • Indicated for the treatment of adult patients with moderately to severely active Crohn's disease • Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Required Medical Information	• For Plaque Psoriasis or Psoriatic Arthritis: ○ Patient's age is 6 years or older. ○ A NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment. ○ Previous treatment failure, intolerance, or contraindication to at least a Tumor necrosis factor (TNF) inhibitor (e.g. etanercept, adalimumab) • For Crohn's Disease or Ulcerative Colitis: ○ A NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment. ○ Previous treatment failure, intolerance, or contraindication to at least a Tumor necrosis factor (TNF) inhibitor (e.g. adalimumab, infliximab) or documented corticosteroid-refractoriness or dependency.
Coverage Duration	One (1) year
Max Quantity Per Day/Month	1 prefilled syringe (45 mg/05mL or 90 mg/1mL)
Max Refills Per Year	Six (6) Refills

Medication	**USTENKINUMAB-KFCE (YESINTEK PREFILLED SYRINGE 45MG/0.5ML, PREFILLED SYRINGE 90MG/ML)**
Required Information for Previous Trials of Rx	None
Other Criteria	IV infusion for initial dose should be accessed through medical benefit with PCP referral

Medication	**LEUPROLIDE ACETATE (ELIGARD 7.5 MG, 22.5 MG, 30 MG, 45 MG)**
Covered Uses	All FDA approved indications: • Indicated for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease on dialysis.
Required Medical Information	• First Prescription Only: Document Diagnosis of advanced prostate cancer
Age Restriction	None
Coverage Duration	One (1) year
Max Quantity Per Day/Month	Eligard 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, and 45 mg for 6-month administration
Max Refills Per Year	Twelve (12) Refills
Required Information for Previous Trials of Rx	None
Other Criteria	• Administration frequency depends on the product being dispensed • Note: This agent is ordinarily administered at the physician's office. For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary

Effective Immediately, the following medication will be removed from the formulary:

- Skyrizi vial – The pen and syringe remain on the formulary but Yesintek will be preferred
  - The vial will remain available until 8/1/2025 for any member who already has approval, but Yesintek will be preferred IL 12/23 inhibitor for future requests.

Medication	**RISANKIZUMAB-RZAA (SKYRIZI 150 MG/ML PEN | SKYRIZI 150 MG/ML SYRINGE)**
Covered Uses	FDA approved indications: • Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy • Indicated for the treatment of active psoriatic arthritis in adults • For other indications see criteria for preferred Stelara Biosimilar, Yesintek

Medication	**RISANKIZUMAB-RZAA (SKYRIZI 150 MG/ML PEN | SKYRIZI 150 MG/ML SYRINGE)**
Exclusion Criteria	None
Required Medical Information	• Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy ○ Screen for latent TB infection prior to initiating therapy (negative tuberculin skin test or chest x ray results). ○ Previous treatment, or intolerance of, with Taltz • Indicated for the treatment of active psoriatic arthritis in adults ○ a NEGATIVE tuberculin skin test, or if positive, has received treatment for latent TB prior to treatment. ○ Previous treatment, or intolerance of, with Taltz • For medical necessity requests for other indications, please include why preferred IL-23 inhibitor, Yesintek (PA required) is not appropriate.
Coverage Duration	6 months
Max Quantity /Fill	1 pen or syringe per fill
Max Refills Per Year	Five (5) refills per year
Required Information for Previous Trials of Rx	A trial, or failure, of a medication is defined by a minimum sixty (60) day trial, UNLESS there is a contraindication to that medication
Other Criteria	None

Effective immediately, the following medications will have updates or minor corrections made to their PA criteria:

- Rinvoq – Updated indications to add giant cell arteritis and updated wording for several indication to directly align with wording in package insert
- Etanercept – Added JPsA indication
- Ezetimibe-Simvastatin – updated indication to directly quote the package insert
- Leuprolide (Lupron) – minor grammar updates for clarification, added criteria for central precocious puberty diagnosis
- Fentanyl, Extended Release Oxycodone, Extended Release Morphine, Methadone (when used for pain) – Minor correction: Updated the Max Refills Per Year field to Not Applicable
- Extended Tramadol– Minor correction: Updated the wording of the indication to quote from the package insert “Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate”; Updated the Max Refills field to reflect that limits for schedule IV are 5 refills in with 6 months

Prior Authorization Criteria:

Medication	**UPADACITINIB (RINVOQ ER 15 MG TABLET | RINVOQ ER 30 MG TABLET | RINVOQ ER 45 MG TABLET | RINVOQ LQ 1 MG/ML SOLUTION)**
Covered Uses	All FDA approved indications: • **Rinvoq:** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with moderately to severely active rheumatoid arthritis (RA). • **Rinvoq/RinvoqLQ**: 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). • **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). • **Rinvoq** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with moderately to severely active ulcerative colitis (UC). • **Rinvoq** is indicated for the treatment of adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers. • **Rinvoq** Treatment of adult patients, who have had an inadequate response or intolerance to one or more TNF blockers, with active ankylosing spondylitis (AS). • **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) with objective signs of inflammation. • **Rinvoq/RinvoqLQ**: 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. • **Rinvoq** is indicated for the treatment of adults with giant cell arteritis.
Exclusion Criteria	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 recent NEGATIVE tuberculosis 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

Medication	UPADACITINIB (RINVOQ ER 15 MG TABLET | RINVOQ ER 30 MG TABLET | RINVOQ ER 45 MG TABLET | RINVOQ LQ 1 MG/ML SOLUTION)
	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 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/CD 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 (i) For adult patients with GCA i. Previous treatment, or intolerance of systemic corticosteroids (e.g., prednisone) for more than sixty (60) days; and ii. Previous treatment, or intolerance of Actemra (tocilizumab) for more than sixty (60) days
Age Restriction	(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
Coverage Duration	Six (6) months
Max Quantity Per Day/Month	Limits may be higher for induction dose for some diagnoses, in accordance with package insert information; please include explanation if intent is to exceed 1 tablet per day for maintenance dosing • 30 or 60 EA PER 30 DAYS • 360 ML PER 30 DAYS
Max Refills Per Year	Twelve (12) Refills
Required Information for Previous Trials of Rx	• A trial, or failure, of a medication is defined by a minimum sixty (60) day trial, UNLESS there is a contraindication for that medication

<table>
<tr><td>Medication</td><td>UPADACITINIB (RINVOQ ER 15 MG TABLET | RINVOQ ER 30 MG TABLET | RINVOQ ER 45 MG TABLET | RINVOQ LQ 1 MG/ML SOLUTION)</td></tr>
<tr><td>Other Criteria</td><td>

Provide intended dosing schedule with request, including details of initial dose and maintenance dose
The tuberculosis test should be within 12 months of the request date

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>
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GENERIC NAME	ETANERCEPT
LABEL NAME(S)	**(ENBREL 25 MG KIT | ENBREL 25 MG/0.5 ML SYRINGE | ENBREL 25 MG/0.5 ML VIAL | ENBREL 50 MG/ML MINI CARTRIDGE | ENBREL 50 MG/ML SURECLICK | ENBREL 50 MG/ML SYRINGE)**
Covered Uses	All FDA approved indications: ● Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA) ● Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older ● Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA) ● Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS) ● Indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy ● Indicated for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older
Required Medical Information	● **For all indications listed above – for the first prescription and every 12 months:** ○ The patient had a recent NEGATIVE tuberculosis test, or if positive, has received treatment for latent TB prior to Enbrel therapy; and ○ The patient does not have a clinically important active infection ● **Additional criteria for moderately to severely active rheumatoid arthritis (RA):** ○ The patient has failed or is intolerant to one formulary NSAID and ○ The patient has failed or is intolerant to one formulary DMARD ● **Additional criteria for active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older**

	○ The patient has failed or is intolerant to one formulary DMARD • **Additional criteria for Plaque Psoriasis**: ○ Involvement of > 10% body surface area (BSA)
Coverage Duration	Six (6) months
Max Quantity Per Month	9.15ML PER 30 DAYS
Max Refills Per Year	Twelve (12) Refills
Required Information for Previous Trials of Rx	• A trial, or failure, of a medication is defined by a minimum sixty (60) day trial, UNLESS there is a contraindication that medication
Other Criteria	• Provide intended dosing schedule with request, including details of starting dose and maintenance dose, where applicable • The tuberculosis test should be within 12 months of the request date

GENERIC NAME	EZETIMIBE/SIMVASTATIN
LABEL NAME(S)	**(EZETIMIBE-SIMVASTATIN 10-10 MG | EZETIMIBE-SIMVASTATIN 10-10 MG | EZETIMIBE-SIMVASTATIN 10-20 MG | EZETIMIBE-SIMVASTATIN 10-20 MG | EZETIMIBE-SIMVASTATIN 10-40 MG | EZETIMIBE-SIMVASTATIN 10-40 MG | EZETIMIBE-SIMVASTATIN 10-80 MG)**
Covered Uses	All FDA approved indications: • As an adjunct to diet to reduce elevated low density lipoprotein cholesterol (LDL-C): ○ In adults with primary hyperlipidemia. ○ In adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). • As an adjunct to other LDL-C-lowering therapies to reduce elevated LDL-C in adults with homozygous familial hypercholesterolemia (HoFH).
Required Medical Information	• Indicated for the reduction of low-density lipoprotein cholesterol (LDL-C): ○ Failure of generic fenofibrate 48, 54, 154, or 160 mg after a period of at least two months on the maximum dose appropriate and tolerated by the patient • Indicated for the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable ○ Failure of generic fenofibrate 48, 54, 154, or 160 mg after a period of at least two months on the maximum dose appropriate and tolerated by the patient
Coverage Duration	Six (6) fills

Max Quantity Per Month	30EA PER 30 DAYS
Max Refills Per Year	Twelve (12) Refills
Required Information for Previous Trials of Rx	A trial, or failure, of a medication is defined by a minimum sixty (60) day trial, UNLESS there is a contraindication that medication
Other Criteria	

Medication	**LEUPROLIDE ACETATE (LUPRON DEPOT 11.25 MG 3MO KIT | LUPRON DEPOT 22.5 MG 3MO KIT | LUPRON DEPOT 3.75 MG KIT | LUPRON DEPOT 45 MG 6MO KIT | LUPRON DEPOT 7.5 MG KIT | LUPRON DEPOT-4 MONTH KIT)**
Covered Uses	All FDA approved indications: • Indicated for the treatment of advanced prostatic cancer • Indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions • Indicated for the preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary • Indicated for the treatment of pediatric patients with central precocious puberty (CPP) Under Maryland's Medicaid Gender-Affirming Treatment Services Program: • For medical treatment of transgender care
Exclusion Criteria	None
Required Medical Information	• Indicated for the treatment of advanced prostatic cancer ○ Diagnosis of advanced prostate cancer, • Indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions ○ For the diagnosis of endometriosis, failure of NSAIDS and oral contraceptives or endometriosis diagnosed by laparoscopy • Indicated for the preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary ○ Diagnosis of fibroids • Indicated for the treatment of pediatric patients with central precocious puberty (CPP) ○ First Prescription Only: ▪ Diagnosis of advanced precocious puberty (a) Positive pubertal response to a GnRH stimulation test. (b) Girl: document of secondary sexual characteristics earlier than 8 years of age.

Medication	**LEUPROLIDE ACETATE (LUPRON DEPOT 11.25 MG 3MO KIT | LUPRON DEPOT 22.5 MG 3MO KIT | LUPRON DEPOT 3.75 MG KIT | LUPRON DEPOT 45 MG 6MO KIT | LUPRON DEPOT 7.5 MG KIT | LUPRON DEPOT-4 MONTH KIT)**
	(c) Boy: document of secondary sexual characteristics earlier than 9 years of age. (d) Bone age advanced one year beyond the chronological age • For medical treatment of transgender care ○ For initial therapy, submission of medical records (e.g., chart notes, laboratory values) documenting all of the following: ▪ Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) criteria, by a mental health professional with expertise in gender affirming therapy; AND ▪ Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender dysphoria hormone therapy OR Coexisting psychiatric and medical comorbidities or social problems that may interfere with the diagnostic procedures or treatment have been addressed or removed; AND ▪ Current enrollment, attendance, and active participation in psychological and social support treatment program ○ For renewal, submission of medical records (e.g., chart notes, laboratory values) documenting all the following: ▪ Medication is prescribed by or in consultation with an endocrinologist or a medical provider experienced in gender affirming therapy AND ▪ Current enrollment, attendance, and active participation in psychological and social support treatment program
Age Restriction	None
Coverage Duration	Twelve (12) months
Max Refills Per Year	Administration frequency depends on the product being dispensed
Required Information for Previous Trials of Rx	A trial, or failure, of a medication is defined by a minimum sixty (60) day trial, UNLESS there is a contraindication to that medication
Other Criteria	* Note: This agent is ordinarily administered at the physician's office. For injectable medications administered by a healthcare professional, please refer to the "Specialty Medication Guidelines" in the beginning of this formulary For more information on transgender care, refer to the Gender-Affirming Treatment Services documentation under the Maryland Medicaid Program or on the MCO website at https://jaimedicalsystems.com/providers/pharmacy/

All changes in this notice supercede any previous edits to the formulary.

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.