University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-41 Janus Kinase Inhibitors

Effective Date: 8/27/25

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by UM Health Plan and may not be covered by all UM Health Plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the situation.

Contact UM Health Plan Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not treatment recommendations and should not be used as treatment guidelines.

2.0 Background or Purpose:

Janus Kinase Inhibitors are specialty drugs indicated for several diagnoses and are associated with adverse effects. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of adverse effects, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. General considerations.

   A. Appropriate medication use [must meet one listed below]:

      1. Food and Drug Administration (FDA) approval status [must meet one listed below]:

         a. FDA approved: product, indication, and/or dosage regimen.

         b. Non-FDA approved: compendium support (Lexi comp™) for use of a drug for a non-FDA approved indication or dosage regimen.

      2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

   B. Exclusions.

      1. Excluded Drugs: Litfulo (ritlecitinib), Olumiant (baricitinib), Sotyktu (deucravacitinib).

a. Trial of all preferred formulary agents is required unless all are contraindicated. Each medication trial must result in an inadequate response after four consecutive months or a severe adverse reaction.

2. Concomitant use of prior authorized specialty agents with approval for overlapping indications.

C. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

D. Adherence to requested medication required for re-approval: consistent fill history (at least 80% of days covered) electronically or verbally from the pharmacy.

II. Rheumatology

A. Rheumatoid Arthritis [must meet all listed below]:

1. Age: at least 18 years.

2. Diagnosis and severity: moderate to severe active rheumatoid arthritis.

3. Other therapies: Trials of two disease-modifying anti-rheumatic agents and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated. Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

a. Disease-modifying anti-rheumatic agents: methotrexate, leflunomide, hydrochloroquine, sulfasalazine, azathioprine, and cyclosporine.

b. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, or Simlandi subcutaneous (adalimumab SQ), Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen: Refer to Appendix I for adjustments.

a. Xeljanz oral (tofacitinib):

i. Immediate-release – 5 mg two times daily.

ii. Extended-release – 11 mg daily.

b. Rinvoq oral (upadacitinib): 15 mg daily.

B. Psoriatic Arthritis [must meet all listed below]:

1. Age: at least 2 years.

2. Diagnosis and severity: active psoriatic arthritis.

3. Other therapies: Trials two disease-modifying anti-rheumatic agents and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated. Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

a. Disease-modifying anti-rheumatic agents: methotrexate, leflunomide, hydroxychloroquine, sulfasalazine, azathioprine, and cyclosporine.

b. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, or Simlandi subcutaneous (adalimumab SQ), Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen: Refer to Appendix I for adjustments.

a. Xeljanz oral (tofacitinib):

i. Immediate-release – 5 mg two times daily.

ii. Extended-release – 11 mg daily.

b. Rinvoq oral (upadacitinib):

i. 10 to <20kg – oral solution: 3mg twice daily

ii. 20 to <30kg – oral solution: 4mg twice daily

iii. ≥30kg – oral solution: 6mg daily -or- extended release tablet: 15mg daily

iv. ≥18 years - extended release tablet: 15mg daily

C. Axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) [must meet all listed below]:

1. Age: at least 18 years.

2. Diagnosis and severity: moderate to severe active rheumatoid arthritis.

3. Other therapies: Trials of two disease-modifying anti-rheumatic agents and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated. Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

a. Disease-modifying anti-rheumatic agents: methotrexate, leflunomide, sulfasalazine, azathioprine, and cyclosporine.

b. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, Simlandi subcutaneous (adalimumab SQ); Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen: Refer to Appendix I for adjustments.

a. Xeljanz oral (tofacitinib):

i. Immediate release – 5 mg two times daily.

ii. Extended release – 11 mg daily.

b. Rinvoq oral (upadacitinib): 15 mg daily.

D. Juvenile Idiopathic Arthritis [must meet all listed below]:

1. Age: at least 2 years

2. Diagnosis and severity: juvenile idiopathic arthritis, polyarticular

3. Other therapies: Trials two disease-modifying anti-rheumatic agents and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated.

Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

a. Disease-modifying anti-rheumatic agents: methotrexate, leflunomide, sulfasalazine, azathioprine,and cyclosporine.

b. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, Simlandi, Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen:

a. Rinvoq oral (upadacitinib):

i. 10 to <20 kg – oral solution: 3 mg twice daily

ii. 20 to <30 kg – oral solution: 4 mg twice daily

iii. ≥30 kg – oral solution: 6mg daily -or- extended-release tablet: 15mg daily

E. Approval.

1. Initial: six months.

2. Re-approval: one year, decrease or sustained decrease in disease activity.

III. Inflammatory bowel disease

A. Crohn's Disease [must meet all listed below]:

1. Age: at least 18 years

2. Diagnosis and severity: moderate to severe active Crohn's Disease.

3. Other therapies: Trials of two disease-modifying anti-rheumatic agents and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated. Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

a. Disease-modifying antirheumatic drug: methotrexate and azathioprine.

b. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, Simlandi, Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen (refer to Appendix I for adjustments):

a. Rinvoq oral (upadacitinib):

i. 45mg once daily for 12 weeks, then 15mg or 30mg once daily.

ii. Discontinue if an adequate response is not achieved with the 30 mg dose; use the lowest effective dose needed to maintain response.

B. Ulcerative Colitis [must meet all listed below]:

1. Age: at least 18 years

2. Diagnosis and severity: moderate to severe active Crohn's Disease.

3. Other therapies: Trials of one conventional therapy, one disease-modifying anti-rheumatic agent, and one Tumor Necrosis Factor (TNF) Inhibitor listed below are required unless all are contraindicated. Each trial must result in an inadequate response after four consecutive months of use per medication or a severe adverse reaction.

    a. Conventional therapy: Mesalamine

    b. Disease-modifying antirheumatic drug: methotrexate, azathioprine, sulfasalazine.

    c. TNF inhibitors: adalimumab-adaz, Hadlima, Hyrimoz, Simlandi, Enbrel, Simponi Aria, Inflectra, Renflexis, and infliximab.

4. Dosage regimen (refer to Appendix I for adjustments):

    a. Xeljanz oral (tofacitinib):

        i. Immediate release (IR): 10mg once daily for eight to sixteen weeks, then 5mg to 10mg twice daily depending on response.

        ii. Extended release (ER): 22mg once daily for eight to 16 weeks, then 11mg to 22mg once daily depending on response.

    b. Rinvoq oral (upadacitinib):

        i. 45mg once daily for 12 weeks, then 15mg or 30mg once daily.

        ii. Discontinue if an adequate response is not achieved with the 30 mg dose; use the lowest effective dose needed to maintain response.

C. Approval:

1. Initial: six months.

2. Re-approval: one year, decrease or sustained decrease in disease activity.

IV. Dermatology

A. Atopic Dermatitis [must meet all listed below]:

1. Age:

    a. Rinvoq (upadacitinib): at least 12 (and at least 88 pounds).

    b. Cibinqo (abrocitinib): at least 18 years.

2. Prescriber: dermatologist or allergist.

3. Diagnosis and severity: moderate to severe atopic dermatitis not controlled with topical prescription therapies or if the therapies are not advisable [must meet all listed below]:

    a. Exacerbating factors that could contribute to the member's atopic dermatitis have been evaluated and addressed (e.g., non-compliance, environmental triggers, allergy patch testing, etc.).

    b. Body surface area (BSA): at least 10 percent.

    c. Severity [must meet both below]:

i. Documentation of current pruritus and other symptoms severity (e.g., erythema, edema, xerosis, erosions. excoriations, oozing/crusting, and/or lichenification).

ii. Interfering with routine daily activities (e.g., skin infections, sleep disturbances).

4. Other therapies: Trials of one topical therapy and one systemic therapy below are required unless all are contraindicated. Each trial must result in an inadequate response after two consecutive months of use per topical therapy and four consecutive months of use per systemic therapy, or a severe adverse reaction.

   a. Topical therapies: mid-strength to super-potent corticosteroid, topical calcineurin inhibitor.

   b. Systemic therapies [must meet one below]:

      i. Oral therapies: including methotrexate

      ii. Injectable therapies: including Dupixent (dupilumab) or Adbry (tralokinumab).

5. Dosage Regimen (refer to Appendix I for adjustments):

   a. Rinvoq oral (upadacitinib): 15 mg once daily; may increase to 30mg if inadequate response.

   b. Cibinqo oral (abrocitinib): 100mg once daily. For insufficient response after 12 weeks, increase the dose to 200mg once daily.

B. Approval:

1. Initial: six months.

2. Re-approval: one year; reduced affected body surface area.

4.0 Coding:

COVERED PRODUCTS - PHARMACY BENEFIT		
Brand Name	**Generic Name**	**Prior Approval**
Cibinqo	abrocitinib	Y
Rinvoq	upadacitinib	Y
Xeljanz/Xeljanz XR	tofacitinib	Y

EXCLUDED CODES AND PRODUCTS		
Brand Name	**Generic Name**	**Benefit Plan Reference/Reason**
Litfulo	ritlecitinib	Not a Preferred Agent
Olumiant	baricitinib	Not a Preferred Agent
Sotyktu	deucravacitinib	Not a Preferred Agent

5.0 References, citations &Clinical Resources:

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4. 3rd European evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. Journal of Crohn's and Colitis. 2017;11:3-25.
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12. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. Journal of the American Academy of Dermatology. 2023;89(1). doi:https://doi.org/10.1016/j.jaad.2022.12.029

6.0 Appendices:

See page 9.

7.0 Revision History:

Revision Date	Reason for Revision
12/19	New format, replaced abbreviations, clarified dosage adjustments and UC dose
6/20	Annual review: replaced abbreviations, deleted prescriber type, changed other therapies language, added Xeljanz XR dosage for UC indication, deleted REMs program in safety and monitoring table, added Rinvoq, approved by P&T Committee 8/26/20.
6/21	Annual review, formatting, replaced abbreviations, clarified criteria instructions, added appropriate use section
11/21	Off-cycle review, Listed already excluded drug in the policy
01/22	Off-cycle review, added TNF inhibitor step due to PI; clarified other therapies and added black box warning, added Rinvoq and Xeljanz dosing to Ankylosing Spondylitis (new indication); added Atopic Dermatitis indication
4/22	Off-cycle review, added Rinvoq for Ulcerative colitis, Atopic dermatitis, and Ankylosing Spondylitis (as well as Xeljanz)
7/22	With approval spelled abbrev and added specialty org references
11/22	Added Cibinqo and IL trial requirement for Atopic Derm

Revision Date	Reason for Revision
3/23	Off-cycle review; adjusted dermatology and other therapy requirements. IBD – added Crohn's disease section (expected new indication for Rinvoq), ulcerative colitis other therapies: removed Enbrel and replaced sulfasalazine with azathioprine. Added Ulcerative Colitis guideline reference.
6/23	Annual review; updated other therapies language, pharmaceutical samples use not accepted, added adherence requirement for re-approval
3/24	Off-cycle review: Added standard language to the general considerations section to align with the new criteria format. Added methotrexate as a trial option for atopic derm systemic therapies. Removed appendix II: Monitoring &Patient Safety to align with new format. Non-contextual formatting edits. Added guideline references.
7/24	Annual Review
6/25	Annual Review, aligning other therapies for disease state with other policies, modify adalimumab biosimilar products covered

Appendix I: Dosage Adjustment

State	Value	Recommendation
Anemia	Hemoglobin (Hgb) at least 9g/dL and decreased less than 2g/dL	Maintain dose
	Hgb less than 8g/dL or decreased more than 2 g/dL	Stop dosing until Hgb normalizes
Lymphopenia	Lymphocyes at least 500 cells/mm^3	Maintain dose
	Lymphocyes less than 500 cells/mm^3	Discontinue
Neutropenia	Absolute neutrophil count (ANC) more than 1000 cells/mm^3	Maintain dose
	ANC 500 to 1000 cells/mm^3	Persistent decrease: stop dosing until ANC is more than 1000 cells/mm^3 then resume normal dose
	ANC less than 500 cells/mm^3	Discontinue
Concurrent CYP450	Potent CYP 3A4 Inducer (rifampin)	Not recommended
	Potent inhibitor (ketoconazole) or more than one moderate CYP 3A4 inhibitor. Potent CYP2C19 inhibitor (fluconazole)	Reduce dose
Renal Function	Mild impairment	No adjustment
	Moderate to severe impairment	Xeljanz: 5mg once daily Rinvoq: 15mg once daily Cibinqo: decrease dose by 50%
	Dialysis	Not recommended
Hepatic Function	Mild impairment	No adjustment
	Moderate impairment	Xeljanz: 5mg once daily Rinvoq: 15mg once daily Cibinqo: no adjustment
	Severe impairment	Not recommended