Janus Kinase Inhibitors

Adjudication Guideline

Rule Category: Pharmaceutical	**Ref: No:** 2024-PH-38	**Version Control:** Version No.2	**Effective Date:** 15/07/2024	**Revision Date:** 07/11/2024
Approved by: Daman	**Responsible:** Pharmacy Standards & Governance	**Related Adjudication Guidelines:**		

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1. Abstract

1.1 For Members

Janus Kinase inhibitors are drugs used to treat moderate to severe chronic inflammatory autoimmune disease like Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Crohn's disease, Ulcerative Colitis, Alopecia Areata and Atopic Dermatitis, Janus Kinase drugs may not be used as a first line treatment.

1.2 For Medical Professionals

JAK inhibitors (JAKi) are a type of immune modulating medication, which inhibits the activity of one or more of the Janus kinase family of enzymes
(JAK1, JAK2, JAK3, TYK2), thereby interfering with the JAK-STAT signaling pathway in lymphocytes. JAKi offer an alternative treatment option for moderate to severe autoimmune diseases, particularly for patients who have failed to respond to or are intolerant of conventional therapies.

2. Scope

Scope of this adjudication rule is to highlight the medical indications, and coverage details of JAKi drugs (Abrocitinib, Baricitinib, Filgotinib, Tofacitinib and Upadacitinib) as per policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Janus Kinase inhibitors are drugs used to treat moderate to severe chronic inflammatory autoimmune disease. like Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, Crohn's disease, Ulcerative Colitis, Alopecia Areata and Atopic Dermatitis, Janus Kinase drugs may not be used as a first line treatment.

Treatment evaluation:

- Patients who have failed prior lines of treatment* may consider treatment with JAK inhibitors.
- Prior lines include the following:
    - **DMARDs OR Biological medications – Autoimmune disease*
    - **Topical Calcineurin inhibitors – Atopic Dermatitis*
    - **Topical Corticosteroids, Topical Minoxidil – Alopecia Areata*
- Ensure disease activity score index marks a moderate to severe disease activity.
- Related lab test should be documented in the medical report for evaluation along with the disease activity score index.
- History of medication must be documented in the medical report.

ACCEPTABLE DISEASE ACTIVITY INDEX SCORING

Medical condition	Accepted Disease Score Activity index
Rheumatoid Arthritis	DAS >3.2 moderate to severe
Ankylosing Spondylitis	CDAI >10, ASDAS >2.1 moderate to severe
Juvenile Idiopathic Arthritis	VAS <6
Psoriatic Arthritis	PsARC number of swollen and tender joints over 68, DAS28 >3.2 DAPSA >15, SDAI >11 moderate to severe.
Ulcerative Colitis	UCDAI >11 Moderate to severe
Crohn's disease	CDAI >220
Atopic Dermatitis	ADSI/SCORAD >2 and EASI >25 moderate to severe
Alopecia Areata	AASI, SALT >50%

Dosage and Administration:
The recommended dose of JAKi drugs as per labelled indications and dose:

Medical condition	JAKi option	Dose at initiation	Maintenance dose	Dose Optimizing
Rheumatoid Arthritis	Baricitinib	2 mg once daily	2 mg once daily	4 mg once daily
	Filgotinib	200 mg once daily	200 mg Once daily	NA
	Tofacitinib	5 mg twice daily **OR** 11 mg Once daily	5 mg twice daily **OR** 11 mg Once daily	NA
	Upadacitinib	15 mg Once daily	15 mg Once daily	NA
Ankylosing Spondylitis	Tofacitinib	5 mg twice daily **OR** 11 mg Once daily	5 mg twice daily **OR** 11 mg Once daily	NA
	Upadacitinib	15 mg Once daily	15 mg Once daily	NA
Psoriatic Arthritis	Tofacitinib	5 mg twice daily **OR** 11 mg Once daily	5 mg twice daily **OR** 11 mg Once daily	NA
	Upadacitinib	15 mg Once daily	15 mg Once daily	NA
Juvenile Idiopathic Arthritis	Tofacitinib	5 mg twice daily	5 mg twice daily	NA
Ulcerative Colitis	Filgotinib	200 mg once daily	200 mg Once daily	NA
	Tofacitinib	10 mg twice daily OR	5 mg twice daily **OR**	10 mg twice daily OR

		22 mg Once daily	11 mg Once daily	22 mg Once daily *(limited to the shortest duration)*
	Upadacitinib	45 mg once daily	15 mg or 30 mg Once daily	NA
Crohn's Disease	Upadacitinib	45 mg once daily	15 mg or 30 mg Once daily	NA
Atopic Dermatitis *(moderate to severe)*	Abrocitinib	100 mg once daily	100 mg once daily	200 mg once daily
	Upadacitinib	15 mg or 30 mg Once daily	15 mg or 30 mg Once daily	NA
Alopecia Areata *(severe)*	Baricitinib	2 mg once daily	2 mg once daily	4 mg once daily

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible Clinician Specialties.

Eligible Ordering Clinicians per Generics				
Abrocitinib	**Baricitinib**	**Filgotinib**	**Tofacitinib**	**Upadacitinib**
Dermatology	Internal Medicine	Internal Medicine	Internal Medicine	Dermatology
Pediatric Dermatology	Allergy	Gastroenterology	Rheumatology	Pediatric Dermatology
Immunology	Dermatology	Rheumatology	Immunology	Immunology
Pediatrics	Rheumatology	immunology and allergy	Immunology and Allergy	Allergy
Adolescent Medicine	Immunology	Immunology	Adolescent Medicine	Gastroenterology
immunology and allergy	Immunology and Allergy		Pediatrics	Immunology and Allergy
Internal Medicine			Pediatric Rheumatology	Immunology
Allergy			Allergy	Rheumatology
			Immunology and Allergy	Internal Medicine
			Gastroenterology	Pediatric
			Pediatrics/ Allergy	Pediatrics/ Allergy

3.3 Non-Coverage

- Visitor Plan
- Basic Plan

3.4 Payment and Coding Rules

Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
MNEC-003	Service is not clinically indicated based on good clinical practice~MNEC-003
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities~MNEC-004
MNEC-005	Service/supply may be appropriate, but too frequent~MNEC-005
MNEC-006	Alternative service should have been utilized~MNEC-006
CODE-010	Activity/diagnosis inconsistent with clinician specialty~CODE-010

5. Appendices

5.1 References

Janus kinase inhibitors (JAKi) - referral | European Medicines Agency (europa.eu)
JAK Inhibitors for Rheumatoid Arthritis (webmd.com)
JAK Inhibitors in Rheumatoid Arthritis: An Evidence-Based Review on the Emerging Clinical Data - PMC (nih.gov)
label (fda.gov) label (fda.gov)
DAS28-ESR for Rheumatoid Arthritis (medscape.com)
Janus kinase inhibitors (JAKi) - referral | European Medicines Agency (europa.eu)
JAK inhibitors art 20_public health communication_post EC decision (europa.eu)
Jyseleca, INN-filgotinib (europa.eu)
label (fda.gov)
Crohn's Disease Activity Index (CDAI) (medscape.com)
Scoring systems in dermatology - Indian Journal of Dermatology, Venereology and Leprology (ijdvl.com)
ASDAS-CRP (Ankylosing Spondylitis Disease Activity Score) (medscape.com)
Psoriasis Area and Severity Index (PASI) Objectivisation by Flow Cytometry Analysis of Major Lymphocytes Subsets - PMC (nih.gov)
Outcome Measures of Disease Severity in Atopic Eczema | Allergy and Clinical Immunology | JAMA Dermatology | JAMA Network
Rheumatoid arthritis - Treatment algorithm | BMJ Best Practice

Juvenile idiopathic arthritis - Treatment algorithm | BMJ Best Practice
Crohn's disease - Treatment algorithm | BMJ Best Practice
Ulcerative colitis - Treatment algorithm | BMJ Best Practice
Janus Kinase inhibitors - DHPC and Communication plan (europa.eu)
label (fda.gov) label (fda.gov)
Jyseleca 100 mg film-coated tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) LABEL (fda.gov)
ORENCIA U.S. Prescribing Information (bms.com)
Olumiant 2 mg Film-Coated Tablets - Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk)
XELJANZ 5 mg film-coated tablets - Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk)
labeling.pfizer.com/ShowLabeling.aspx?id=16652
Cibinqo 100 mg film-coated tablets - Summary of Product Characteristics (SmPC) (emc) (medicines.org.uk) Jyseleca, INN-filgotinib (europa.eu)
Alopecia areata - Treatment algorithm | BMJ Best Practice
Alopecia areata - Emerging treatments | BMJ Best Practice
Contact dermatitis - Treatment algorithm | BMJ Best Practice
VALIDITY OF OUTCOME MEASURES - Budesonide (Cortiment MMX) - NCBI Bookshelf (nih.gov)
Treating Psoriatic Arthritis to Target: Defining Psoriatic Arthritis Disease Activity Score (PASDAS) That Reflects State Of Minimal Disease Activity (MDA) | The Journal of Rheumatology (jrheum.org)
Clinical outcome measures in juvenile idiopathic arthritis | Pediatric Rheumatology | Full Text (biomedcentral.com)
https://www.ema.europa.eu/en/medicines/human/referrals/janus-kinase-inhibitors-jaki#overview https://www.gov.uk/drug-safety-update/janus-kinase-jak-inhibitors-new-measures-to-reduce-risks-of-major-cardiovascularevents-malignancy-venous-thromboembolism-serious-infections-and-increased-mortality https://www.aad.org/public/diseases/a-z/jak-inhibitors

5.2 Revision History

Date	Version No.	Change(s)
11/06/2024	V1.0	Creation of Adjudication Guideline-External Instruction Template.
07/11/2024	V2.0	Content update – treatment line tagging removed from the table, additional note treatment evaluation added.