JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS089
		Effective Date	01/17/2024
		Approval Date	01/17/2024
	Subject **Oral Biological Modifiers (Otezla, Xeljanz, Olumiant, Rinvoq, Sotyktu)**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Olumiant, Otezla, Rinvoq, Sotyktu, Xeljanz

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I. POLICY

A. Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), and Sotyktu (deucravacitinib) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Otezla** may be approved for the following:

1. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of active psoriatic arthritis
   c. Patient has had trial and insufficient response to at least two DMARDs, including methotrexate, unless contraindicated
   d. Patient has had trial and insufficient response to etanercept, adalimumab, or secukinumab
2. **Plaque Psoriasis**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of moderate to severe plaque psoriasis with one of the following:
      I. Body surface area involvement of >10%

II. Body surface area involvement of ≤10%, but involves sensitive areas (palms/soles of feet, genitalia, or head.neck)

c. Patient has had trial and insufficient response or contraindication to at least one of the following:
   I. Phototherapy
   II. Systemic therapy with methotrexate or cyclosporine
   III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogues, or retinoids) is required, unless their use is contraindicated.

d. Patient has had trial and insufficient response to brodalumab, etanercept, adalimumab, or secukinumab

3. **Behcet's Disease**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of Behcet's disease associated oral ulcers
   c. Patient has at least two oral ulcers
   d. Patient has had trial and insufficient response to at least one non-biologic agent (oral or topical corticosteroids, colchicine)

B. **Xeljanz** may be approved for the following:
   1. **Rheumatoid Arthritis**
      a. Patient is 18 years of age or older
      b. Documentation has been provided showing a diagnosis of moderate to severe rheumatoid arthritis
      c. Patient has had trial and insufficient response to methotrexate monotherapy, unless contraindicated
      d. Patient has had trial and insufficient response with etanercept or adalimumab
   2. **Psoriatic Arthritis**
      a. Patient is 18 years of age or older
      b. Documentation has been provided showing a diagnosis of active psoriatic arthritis
      c. Patient has had trial and insufficient response to at least two DMARDs, including methotrexate, unless contraindicated
      d. Patient has had trial and insufficient response to etanercept, adalimumab, or secukinumab
   3. **Polyarticular Course Juvenile Idiopathic Arthritis**
      a. Patient is 2 years of age or older
      b. Documentation has been provided showing a diagnosis of active polyarticular course juvenile idiopathic arthritis
      c. Patient has had trial and insufficient response to at least one DMARD, such as methotrexate, unless contraindicated
      d. Patient has had trial and insufficient response to either etanercept or adalimumab
   4. **Ulcerative Colitis**
      a. Patient is 18 years of age or older
      b. Documentation has been provided showing a diagnosis of moderately to severely active ulcerative colitis
      c. Patient has had trial and insufficient response to adalimumab
   5. **Ankylosing Spondylitis**
      a. Patient is 18 years of age or older
      b. Patient has had trial and insufficient response to an adequate trial of two full dose NSAID therapies, unless contraindicated
      c. Patient has had trial and insufficient response to either etanercept or adalimumab

C. **Xeljanz Oral Solution** may be approved for the following:

1. **Polyarticular Course Juvenile Idiopathic Arthritis**
   a. Patient is 2 years of age or older
   b. Documentation has been provided showing a diagnosis of active polyarticular course juvenile idiopathic arthritis
   c. Patient has had trial and insufficient response to at least one DMARD, such as methotrexate, unless contraindicated
   d. Patient has had trial and insufficient response to either etanercept or adalimumab

D. **Olumiant** may be approved for the following:
1. **Rheumatoid Arthritis**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of moderate to severe rheumatoid arthritis
   c. Patient has had trial and insufficient response to methotrexate monotherapy, unless contraindicated
   d. Patient has had trial and insufficient response to etanercept, adalimumab, or tofacitinib

E. **Rinvoq** may be approved for the following:
1. **Rheumatoid Arthritis**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of moderate to severe rheumatoid arthritis
   c. Patient has had trial and insufficient response to methotrexate monotherapy, unless contraindicated
   d. Patient has had trial and insufficient response to etanercept, adalimumab, or tofacitinib
2. **Psoriatic Arthritis**
   a. Patient is 18 years of age or older
   b. Documentation has been provided showing a diagnosis of active psoriatic arthritis
   c. Patient has had trial and insufficient response to at least two DMARDs, including methotrexate, unless contraindicated
   d. Patient has had trial and insufficient response to etanercept, adalimumab, or secukinumab
3. **Atopic Dermatitis**
   a. Patient is 12 years of age or older
   b. Patient has a confirmed diagnosis of refractory, moderate to severe chronic atopic dermatitis with documented BSA coverage of 10% or greater.
   c. Patient has documented functional impairment as a result of chronic atopic dermatitis, which can include limitation of activities of daily living (ex. consistent sleep disturbances, problems wearing clothing, skin infections, etc.)
   d. Documentation has been provided showing a baseline assessment using one of the following tools:
      I. Investigator's Static Global Assessment (ISGA) score
      II. Eczema Area and Severity Index (EASI)
      III. Patient-Oriented Eczema Measure (POEM)
      IV. Scoring Atopic Dermatitis (SCORAD) index
   e. Patient has a documented history of treatment failure, contraindication, or intolerance to both of the following formulary alternatives:
      I. Two medium to very-high potency topical corticosteroids
      II. One topical calcineurin inhibitor [ex. Elidel (pimecrolimus) or Protopic (tacrolimus)]
      III. Caveat for patients with moderate disease:
         i. In addition to trials of topical corticosteroids and a calcinuerin inhibitor, documentation of trial and inadequate response to Eucrisa (crisaborole) is required.

f. Patient has had trial and inadequate response to phototherapy, unless such use is not advised (i.e. patient has a history of skin cancer history, currently taking medication that may be photosensitizing, etc.)
g. Patient has had trial and inadequate response to at least one of the following systemic agents traditionally used for refractory disease, or has a contraindication to systemic therapy:
    I. cyclosporine
    II. methotrexate
    III. mycophenolate mofetil
    IV. azathioprine
h. Patient is not being concomitantly treated with other biologics (Enbrel, Xolair, Rituxan, Adbry etc.), JAK inhibitors (Cibinqo, etc.), or other immunosuppressants
i. Prescriber is one of the following specialists: Allergist, Dermatologist, or Immunologist

4. **Ulcerative Colitis**
    a. Patient is 18 years of age or older
    b. Documentation has been provided showing a diagnosis of moderately to severely active ulcerative colitis
    c. Patient has had trial and insufficient response to adalimumab
5. **Crohn's Disease**
    1. Patient is 18 years of age or older
    2. Patient has been diagnosed with moderately to severely active Crohn's disease
    3. Patient has tried and had insufficient response with conventional therapies corticosteroids, or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate
    4. Patient has had trial and insufficient response, or intolerance to adalimumab or infliximab
6. **Ankylosing Spondylitis**
    a. Patient is 18 years of age or older
    b. Patient has had trial and insufficient response to an adequate trial of two full dose NSAID therapies, unless contraindicated
    c. Patient has had trial and insufficient response to either etanercept or adalimumab
7. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)**
    a. Patient is 18 years of age or older
    b. Patient has a diagnosis of adult-onset active non-radiographic axial spondyloarthritis
    c. Patient has objective signs of inflammation indicated by C-reactive protein (CRP) levels above the upper limit of normal OR sacroiliitis on magnetic resonance imaging (MRI)
    d. Patient has had trial and insufficient response to at least two full dose NSAID therapies, unless contraindicated
    e. Patient has had trial and insufficient response to secukinumab

F. **Sotyktu** may be approved for the following:
1. **Plaque Psoriasis**
    a. Patient is 18 years of age or older
    b. Documentation has been provided showing a diagnosis of moderate to severe plaque psoriasis with one of the following:
        I. Body surface area involvement of >10%
        II. Body surface area involvement of ≤10%, but involves sensitive areas (palms/soles of feet, genitalia, or head.neck)
    c. Patient has had trial and insufficient response or contraindication to at least one of the following:
        I. Phototherapy
        II. Systemic therapy with methotrexate or cyclosporine

III. *Caveat for patients with moderate disease: In addition to trials with either phototherapy or systemic therapy, documentation of topical pharmacologic therapy (corticosteroids, vitamin D analogues, or retinoids) is required, unless their use is contraindicated.

d. Patient has had trial and insufficient response to brodalumab, etanercept, adalimumab, or secukinumab

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be restricted to 12-16 weeks based on the indication, requiring follow-up approvals for future prescriptions.

B. Approval for continuation of therapy can be extended in up to 12-month intervals with documentation showing the patient's clinical improvement from treatment as supported by one of the following condition-indicated outcomes:

1. For arthritis indications, ankylosing spondylitis, plaque psoriasis, and nonradiographic axial spondyloarthritis:
   a. Reduction in the signs and symptoms
   b. Prolonged beneficial clinical response
   c. Inhibition of structural damage progression
   d. Improved physical functioning
2. For ulcerative colitis and Crohn's disease:
   a. Reduction in gastrointestinal signs and symptoms
   b. Prolonged clinical remission and mucosal healing
3. For atopic dermatitis, a score reduction using ONE of the following clinical evaluation tools:
   1. ISGA: decrease from baseline by at least 2 points
   2. EASI: decrease from baseline by at least 75%
   3. POEM: decrease from baseline by at least 3 points
   4. SCORAD: decrease from baseline by at least 50%

IV. EXCLUSIONS

A. Otezla, Xeljanz, Olumiant, Rinvoq and Sotyktu will not be approved for the following:
   1. Concurrent use with a biologic DMARD
   2. Any indications, or uses that are not FDA-approved or guideline-supported

B. The use of Xeljanz, Olumiant, Rinvoq, and Sotyktu will also not be approved in combination with other JAK inhibitors, or potent immunosuppressants (such as azathioprine and cyclosporine)

C. Oral biologic modifiers will not be approved for hair growth therapy in accordance with COMAR

D. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Otezla [Prescribing Information] Summit, NJ: Celgene Corporation; 2021 December.
2. Xeljanz [Prescribing Information] New York, NY: Pfizer Labs; 2021 December.
3. Olumiant [Prescribing Information] Indianapolis, IN: Lilly USA LLC; 2022 June.
4. Rinvoq [Prescribing Information] North Chicago, IL: AbbVie Inc; 2023 May.
5. Sotyktu [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; 2022 September.
6. Smith EL, Yazici, Y. Treatment of Behcet syndrome. Merkel, PA (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on December 13, 2019).
7. Rokutanda, R et al. Update on the diagnosis and management of Behçet's disease. Open Access Rheumatology : research and reviews vol. 7 1-8. 30 Dec. 2014. doi:10.2147/OARRR.S46644

8. Hatemi G et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. Annals of the Rheumatic Diseases 2018;77:808-818.
9. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol 2020;82:1445-86.
10. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021 Feb;84(2):432-470.
11. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol 2019;81:775-804.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVSION	SUMMARY OF CHANGE
04/20/2016	Updated Title to reflect formulation
07/27/2017	Updated Exclusions section regarding physician samples
04/18/2018	Updated clinical criteria for Otezla
07/18/2018	Updated indications for Xeljanz
10/17/2018	Added clinical criteria for Olumiant
12/13/2019	Updated criteria layout, clarified current criteria, and added new criteria for Otezla's Behcet's Disease indication per PI
01/08/2020	Added criteria for Rinvoq
01/20/2021	Added clinical criteria for Xeljanz oral solution
02/07/2022	Updated clinical criteria sections based on updated FDAapproved prescribing information
04/20/2022	Updated clinical criteria sections based on updated FDAapproved prescribing information
06/14/2022	Clarified exclusions
07/20/2022	Updated Rinvoq clinical criteria based on new FDA approvals; clarified plaque psoriasis criteria
10/19/2022	Added criteria for Sotyktu; clarified atopic dermatitis criteria
11/07/2022	Updated Rinvoq clinical criteria based on new FDA indication approval

07/19/2023	Updated Rinvoq clinical criteria based on new FDA indication approval

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