

## Clinical Policy: Upadacitinib (Rinvoq, Rinvoq LQ)

Reference Number: PA.CHIP.PHAR.443

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### Description

Upadacitinib (Rinvoq®, Rinvoq LQ®) is a Janus kinase (JAK) inhibitor.

### FDA Approved Indication(s)

Rinvoq and Rinvoq LQ are indicated for treatment of:

- Adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- 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 also indicated for treatment of:

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
- Adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.
- Adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers.

Limitation(s) of use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Upadacitinib (Rinvoq, Rinvoq LQ) is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### I. Initial Approval Criteria

##### A. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (*see Appendix E*);
2. Request is for Rinvoq;

3. Prescribed by or in consultation with a rheumatologist;
4. Age  $\geq 18$  years;
5. Member meets one of the following (a or b):
  - a. Failure of a  $\geq 3$  consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
  - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a  $\geq 3$  consecutive month trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated;
6. Failure of ALL\* of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
  - a. One adalimumab product (e.g., *Hadlima*<sup>™</sup>, *Simlandi*<sup>®</sup>, *Yusimry*<sup>™</sup>, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
  - b. Actemra<sup>®</sup>;
  - c. If member has not responded or is intolerant to one or more TNF blockers, *Xeljanz*<sup>®</sup>/*Xeljanz XR*<sup>®</sup>, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

*\*Prior authorization may be required for adalimumab products, Actemra, and Xeljanz/Xeljanz XR*
7. Documentation of one of the following baseline assessment scores (a or b):
  - a. Clinical disease activity index (CDAI) score (*see Appendix F*);
  - b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix G*);
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed both of the following (a and b):
  - a. 15 mg per day;
  - b. 1 tablet per day.

**Approval duration: 6 months**

**B. Psoriatic Arthritis (must meet all):**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age  $\geq 2$  years;
4. For members  $\geq 18$  years, both of the following (a and b):
  - a. Request is for Rinvoq;
  - b. Failure of ALL of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (i, ii, and iii, *see Appendix D*):
    - i. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
    - ii. Otezla<sup>®</sup>;
    - iii. If member has not responded or is intolerant to one or more TNF blockers, *Xeljanz*/*Xeljanz XR*, unless member has cardiovascular risk and benefits do

not outweigh the risk of treatment;

*\*Prior authorization may be required for adalimumab products, Otezla, and Xeljanz/Xeljanz XR*

5. For age  $\geq 6$  years, failure of a  $\geq 3$  consecutive month trial of one ustekinumab product (e.g. *Otufi*<sup>®</sup>, *Pyzchiva*<sup>®</sup> (branded), *Steqeyma*<sup>®</sup>, *Yesintek*<sup>™</sup> are preferred), unless clinically significant adverse effects are experienced or all are contraindicated;  
*\*Prior authorization may be required for ustekinumab products*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
7. Dose does not exceed one of the following (a or b):
  - a. Age  $\geq 18$  years: Both of the following (i and ii) (*Rinvoq*):
    - i. 15 mg per day;
    - ii. 1 tablet per day;
  - b. Age  $\geq 2$  to  $< 18$  years: One of the following (i, ii, or iii):
    - i. Weight 10 kg to  $< 20$  kg: 6 mg per day (*Rinvoq LQ*);
    - ii. Weight 20 kg to  $< 30$  kg: 8 mg per day (*Rinvoq LQ*);
    - iii. Weight  $\geq 30$  kg, one of the following (1 or 2):
      - 1) 12 mg per day (*Rinvoq LQ*);
      - 2) Both of the following (a and b) (*Rinvoq*):
        - a) 15 mg per day;
        - b) 1 tablet per day.

**Approval duration: 6 months**

**C. Atopic Dermatitis (must meet all):**

1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
  - a. At least 10% of the member's body surface area (BSA);
  - b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Request is for *Rinvoq*;
3. Prescribed by or in consultation with a dermatologist or allergist;
4. Age  $\geq 12$  years;
5. Failure of both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced:
  - a. Two formulary medium to very high potency topical corticosteroids, each used for  $\geq 2$  weeks;
  - b. One non-steroidal topical therapy\* used for  $\geq 4$  weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or *Eucrisa*<sup>®</sup>;  
*\*These agents may require prior authorization*
6. *Rinvoq* is not prescribed concurrently with another biologic medication (e.g., *Adbry*<sup>®</sup>, *Dupixent*<sup>®</sup>) or a JAK inhibitor (e.g., *Olumiant*<sup>®</sup>, *Cibinqo*<sup>®</sup>, *Opzelura*<sup>™</sup>);
7. Dose does not exceed one of the following (a or b):
  - a. Both of the following (i and ii):
    - i. 15 mg per day;
    - ii. 1 tablet per day;
  - b. Medical justification supports inadequate response to 15 mg daily and both of the following (i and ii):
    - i. 30 mg per day;
    - ii. 1 tablet per day.

**Approval duration: 6 months**

**D. Axial Spondyloarthritis (must meet all):**

1. Diagnosis of AS or nr-axSpA;
2. Request is for Rinvoq;
3. Prescribed by or in consultation with a rheumatologist;
4. Age  $\geq 18$  years;
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for  $\geq 4$  weeks unless clinically significant adverse effects are experienced or all are contraindicated;
6. For AS: Failure of ALL of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, *see Appendix D*):
  - a. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
  - b. If member has not responded or is intolerant to one or more TNF blockers, *Xeljanz/Xeljanz XR*, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

*\*Prior authorization may be required for adalimumab products and Xeljanz/Xeljanz XR*

7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed both of the following (a and b):
  - a. 15 mg per day;
  - b. 1 tablet per day.

**Approval duration: 6 months**

**E. Ulcerative Colitis (must meet all):**

1. Diagnosis of UC;
2. Request is for Rinvoq;
3. Prescribed by or in consultation with a gastroenterologist;
4. Age  $\geq 18$  years;
5. Documentation of a Mayo Score  $\geq 6$  or modified Mayo Score  $\geq 5$  (*see Appendix H*);
6. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
7. Failure of one of the following, used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a or b):
  - a. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
  - b. One ustekinumab product (e.g. *Otulf®*, *Pyzchiva®* (branded), *Steqeyma®*, *Yesintek™* are preferred);

*\*Prior authorization may be required for adalimumab products and ustekinumab products*

8. Member has not responded or is intolerant to one or more TNF blockers, unless contraindicated;

*\*Prior authorization may be required for TNF blockers*

9. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
10. Request meets one of the following (a or b):
  - a. For induction (both i and ii):
    - i. 45 mg once daily for 8 weeks;
    - ii. 1 tablet once daily for 8 weeks;
  - b. For maintenance (both i and ii):
    - i. 15 mg once daily;
    - ii. 1 tablet once daily.

**Approval duration: 6 months**

**F. Crohn's Disease (must meet all):**

1. Diagnosis of CD;
2. Request is for Rinvoq;
3. Prescribed by or in consultation with a gastroenterologist;
4. Age  $\geq$  18 years;
5. Member meets one of the following (a or b):
  - a. Failure of a  $\geq$  3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - b. Medical justification supports inability to use immunomodulators (*see Appendix I*);
6. Member meets one of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or b, *see Appendix D*):\*
  - a. Failure of one adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), used for  $\geq$  3 consecutive months;
  - b. History of failure of two TNF blockers;

*\*Prior authorization may be required for adalimumab products*
7. Failure of a  $\geq$  3 consecutive month trial of one ustekinumab product (e.g. *Otulfi*<sup>®</sup>, *Pyzchiva*<sup>®</sup> (branded), *Steqeyma*<sup>®</sup>, *Yesintek*<sup>™</sup> are preferred), unless clinically significant adverse effects are experienced or all are contraindicated;  
*\*Prior authorization may be required for ustekinumab products*
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Request meets one of the following (a or b):
  - a. For induction (both i and ii):
    - i. 45 mg once daily for 12 weeks;
    - ii. 1 tablet once daily for 8 weeks;
  - b. Medical justification supports inadequate response to 15 mg daily and both of the following (i and ii):
    - i. 30 mg per day;
    - ii. 1 tablet per day.

**Approval duration: 6 months**

**G. Polyarticular Juvenile Idiopathic Arthritis (must meet all):**

1. Diagnosis of PJIA\* as evidenced by  $\geq 5$  joints with active arthritis;  
*\*Overlap of diagnosis exists in children with JIA and non-systemic polyarthritis, which may include children from ILAR JIA categories of enthesitis-related arthritis*
2. Prescribed by or in consultation with a rheumatologist;
3. Age  $\geq 2$  years;
4. Member meets one of the following (a, b, c, or d):
  - a. Failure of a  $\geq 3$  consecutive month trial of MTX at up to maximally indicated doses;
  - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a  $\geq 3$  consecutive month trial of leflunomide or sulfasalazine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
  - c. For sacroiliitis/axial spine involvement (i.e., spine, hip), failure of a  $\geq 4$  week trial of an NSAID at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - d. Documentation of high disease activity;
5. Failure of ALL\* of the following, each used for  $\geq 3$  consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
  - a. ONE adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
  - b. Actemra®;
  - c. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;  
*\*Prior authorization may be required for adalimumab products, Actemra, and Xeljanz*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a, b, or c):
  - a. Weight 10 kg to  $< 20$  kg: 6 mg per day (*Rinvoq LQ*);
  - b. Weight 20 kg to  $< 30$  kg: 8 mg per day (*Rinvoq LQ*);
  - c. Weight  $\geq 30$  kg, one of the following (i or ii):
    - i. 12 mg per day (*Rinvoq LQ*);
    - ii. Both of the following (1 and 2) (*Rinvoq*):
      - 1) 15 mg per day;
      - 2) 1 tablet per day.

**Approval duration: 6 months**

**H. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):



- a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Rheumatoid Arthritis (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Request is for Rinvoq;
3. Member is responding positively to therapy as evidenced by one of the following (a or b):
  - a. A decrease in CDAI (*see Appendix F*) or RAPID3 (*see Appendix G*) score from baseline;
  - b. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
  - a. 15 mg per day;
  - b. 1 tablet per day.

**Approval duration: 12 months**

### B. Atopic Dermatitis (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Request is for Rinvoq;
3. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
4. Rinvoq is not prescribed concurrently with another biologic medication (e.g., Adbry, Dupixent) or a JAK inhibitor (e.g., Olumiant, Cibinqo, Opzelura);
5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
  - a. Both of the following (i and ii):

- i. 15 mg per day;
- ii. 1 tablet per day;
- b. Medical justification supports inadequate response to 15 mg daily and both of the following (i and ii):
  - i. 30 mg per day;
  - ii. 1 tablet per day.

**Approval duration: 12 months**

**C. All Other Indications** (must meet all):

- 1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- 2. For CD, UC, AS, nr-axSpA: Request is for Rinvoq;
- 3. For CD, UC, AS, nr-axSpA, PsA: Member is responding positively to therapy;
- 4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 5. If request is for a dose increase, new dose does not exceed (a, b, c, or d):
  - a. For UC, AS, nr-axSpA: Both of the following (i and ii) (*Rinvoq*):
    - i. 15 mg per day;
    - ii. 1 tablet per day;
  - b. For refractory, severe, or extensive UC or CD: Both of the following (i and ii) (*Rinvoq*):
    - i. 30 mg per day;
    - ii. 1 tablet per day;
  - c. For PsA: One of the following (i or ii):
    - i. Age  $\geq 18$  years: Both of the following (1 and 2) (*Rinvoq*):
      - 1) 15 mg per day;
      - 2) 1 tablet per day;
    - ii. Age  $\geq 2$  to  $< 18$  years: One of the following (1, 2, or 3):
      - 1) Weight 10 kg to  $< 20$  kg: 6 mg per day (*Rinvoq LQ*);
      - 2) Weight 20 kg to  $< 30$  kg: 8 mg per day (*Rinvoq LQ*);
      - 3) Weight  $\geq 30$  kg: One of the following (a or b):
        - a) 12 mg per day (*Rinvoq LQ*);
        - b) Both of the following (i and ii) (*Rinvoq*):
          - i) 15 mg per day;
          - ii) 1 tablet per day;
    - d. For pJIA: One of the following (i, ii, or iii):
      - i. Weight 10 kg to  $< 20$  kg: 6 mg per day (*Rinvoq LQ*);
      - ii. Weight 20 kg to  $< 30$  kg: 8 mg per day (*Rinvoq LQ*);
      - iii. Weight  $\geq 30$  kg, one of the following (1 or 2):
        - 1) 12 mg per day (*Rinvoq LQ*);
        - 2) Both of the following (a and b) (*Rinvoq*):
          - a) 15 mg per day;
          - b) 1 tablet per day.



**Approval duration: 12 months**

**D. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia<sup>®</sup>, Enbrel<sup>®</sup>, Humira<sup>®</sup> and its biosimilars, Remicade<sup>®</sup> and its biosimilars, Simponi<sup>®</sup>], interleukin agents [e.g., Actemra<sup>®</sup> (IL-6RA) and its biosimilars, Arcalyst<sup>®</sup> (IL-1 blocker), Bimzelx<sup>®</sup> (IL-17A and F antagonist), Cosentyx<sup>®</sup> (IL-17A inhibitor), Ilaris<sup>®</sup> (IL-1 blocker), Ilumya<sup>™</sup> (IL-23 inhibitor), Kevzara<sup>®</sup> (IL-6RA), Kineret<sup>®</sup> (IL-1RA), Omvoh<sup>™</sup> (IL-23 antagonist), Siliq<sup>™</sup> (IL-17RA), Skyrizi<sup>™</sup> (IL-23 inhibitor), Spevigo<sup>®</sup> (IL-36 antagonist), Stelara<sup>®</sup> (IL-12/23 inhibitor) and its biosimilars, Taltz<sup>®</sup> (IL-17A inhibitor), Tremfya<sup>®</sup> (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinco<sup>™</sup>, Olumiant<sup>™</sup>, Rinvoq<sup>™</sup>, Xeljanz<sup>®</sup>/Xeljanz<sup>®</sup> XR,], anti-CD20 monoclonal antibodies [Rituxan<sup>®</sup> and its biosimilars], selective co-stimulation modulators [Orencia<sup>®</sup>], integrin receptor antagonists [Entyvio<sup>®</sup>], tyrosine kinase 2 inhibitors [Sotyktu<sup>™</sup>], and sphingosine 1-phosphate receptor modulator [Velsipity<sup>™</sup>] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AS: ankylosing spondylitis

CD: Crohn's disease

CDAI: clinical disease activity index

DMARD: disease-modifying  
antirheumatic drug

FDA: Food and Drug Administration

JAKi: Janus kinase inhibitors

MTX: methotrexate

nr-axSpA: non-radiographic axial  
spondyloarthritis

PsA: psoriatic arthritis

RA: rheumatoid arthritis

RAPID3: routine assessment of patient  
index data 3

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan <sup>®</sup> , Imuran <sup>®</sup> )	<b>RA</b> 1 mg/kg/day PO QD or divided BID  <b>CD</b> 1.5 – 2 mg/kg/day PO	3 mg/kg/day
corticosteroids	<b>UC*</b> Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week  Budesonide (Uceris <sup>®</sup> ) 9 mg PO QAM for up to 8 weeks  <b>CD*</b> <i>Adult:</i> prednisone 40 mg – 60 mg PO QD for 1 to 2 weeks, then taper daily dose by 5 mg weekly until 20 mg PO QD, and then continue with 2.5 – 5 mg decrements weekly or IV 50 – 100 mg Q6H for 1 week  budesonide (Entocort EC <sup>®</sup> ) 6 – 9 mg PO QD  <i>Pediatric:</i> Prednisone 1 to 2 mg/kg/day PO QD	Various

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cuprimine® (d-penicillamine)	<b>RA*</b> <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	<b>RA</b> 2.5 – 4 mg/kg/day PO divided BID	RA: 4 mg/kg/day
hydroxychloroquine (Plaquenil®)	<b>RA*</b> <u>Initial dose:</u> 400 – 600 mg/day PO QD <u>Maintenance dose:</u> 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	<b>RA</b> <u>Initial dose (for low risk hepatotoxicity or myelosuppression):</u> 100 mg PO QD for 3 days <u>Maintenance dose:</u> 20 mg PO QD  <b>PJIA*</b> Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
6-mercaptopurine (Purixan®)	<b>CD*</b> 50 mg PO QD or 0.75 – 1.5 mg/kg/day PO	1.5 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	<b>RA</b> 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week  <b>CD*</b> 15 – 25 mg/week IM or SC  <b>PJIA*</b> 10 – 20 mg/m <sup>2</sup> /week PO, SC, or IM	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	<b>AS</b> Varies	Varies
Pentasa® (mesalamine)	<b>CD</b> 1,000 mg PO QID	4 g/day
Ridaura®	<b>RA</b>	9 mg/day (3 mg TID)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(auranofin)	6 mg PO QD or 3 mg PO BID	
sulfasalazine (Azulfidine <sup>®</sup> )	<p><b>RA</b>  <u>Initial dose:</u>                      500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day.  <u>Maintenance dose:</u>                      2 g/day PO in divided doses</p> <p><b>PJIA*</b>                      30-50 mg/kg/day PO divided BID</p>	<p>3 g/day</p> <p>PJIA: 2 g/day</p>
Actemra <sup>®</sup> (tocilizumab)	<p><b>RA</b>                      IV: 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response</p> <p><b>SC:</b>                      Weight &lt; 100 kg: 162 mg SC every other week, followed by an increase to every week based on clinical response                      Weight ≥ 100 kg: 162 mg SC every week</p> <p><b>pJIA</b>                      • Weight &lt; 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks                      • Weight ≥ 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks</p>	<p><b>RA:</b>                      IV: 800 mg every 4 weeks                      SC: 162 mg every week</p> <p><b>PJIA:</b>                      • IV: 10 mg/kg every 4 weeks                      • SC: 162 mg every 2 weeks</p>
Cimzia <sup>®</sup> (certolizumab)	<p><b>nr-axSpA</b>  <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks  <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)</p> <p><b>CD</b>  <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks  <u>Maintenance dose:</u> 400 mg SC every 4 weeks</p>	400 mg every 4 weeks
Hadlima (adalimumab-bwwd), Simlandi	<p><b>CD, UC</b>  <u>Initial dose:</u></p>	40 mg every other week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(adalimumab-ryvk), Yusimry (adalimumab-aqv), adalimumab-aaty (Yuflyma <sup>®</sup> ), adalimumab-adaz (Hyrimoz <sup>®</sup> ), adalimumab-fkjp (Hulio <sup>®</sup> ), adalimumab-adbm (Cyltezo <sup>®</sup> )	<p>160 mg SC on Day 1, then 80 mg SC on Day 15</p> <p><u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29</p> <p><b>RA, AS, PsA</b> 40 mg SC every other week</p> <p><b>pJIA</b> <b>Cyltezo, Hadlima, Hyrimoz:</b> Weight 10 kg (22 lbs) to &lt; 15 kg (33 lbs): 10 mg SC every other week</p> <p><b>Cyltezo, Hadlima, Hulio, Yuflyma:</b> Weight 15 kg (33 lbs) to &lt; 30 kg (66 lbs): 20 mg SC every other week</p> <p><b>Cyltezo, Hadlima, Hulio, Hyrimoz, Simlandi, Yuflyma, Yusimry:</b> Weight ≥ 30 kg (66 lbs): 40 mg SC every other week</p>	
Otulf <sup>®</sup> (ustekinumab-aauz), Pyzchiva <sup>®</sup> (ustekinumab-ttwe), Steqeyma <sup>®</sup> (ustekinumab-stba), Yesintek <sup>™</sup> (ustekinumab-kfce)	<p><b>CD, UC</b> <u>Weight based dosing IV at initial dose:</u> Weight ≤ 55 kg: 260 mg Weight &gt; 55 kg to 85 kg: 390 mg Weight &gt; 85 kg: 520 mg</p> <p><u>Maintenance dose:</u> 90 mg SC every 8 weeks</p> <p><b>PsA</b> Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks</p> <p><i>Adult:</i> 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks</p> <p><i>Pediatrics (age 6 years to 17 years):</i> Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter</p>	<p>CD, UC: 90 mg every 8 weeks</p> <p>PsA: 45 mg every 12 weeks</p>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<b>Otufi, Pyzchiva, Yesintek:</b> Weight < 60 kg: 0.75 mg/kg  <b>Otufi, Pyzchiva, Steqeyma, Yesintek:</b> Weight ≥ 60 kg: 45 mg	
Taltz® (ixekizumab)	<b>AS, nr-axSpA, PsA</b> <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	<b>AS, PsA, RA</b> 5 mg PO BID  <b>pJIA</b> <ul style="list-style-type: none"> <li>10 kg ≤ body weight &lt; 20 kg: 3.2 mg (3.2 mL oral solution) PO BID</li> <li>20 kg ≤ body weight &lt; 40 kg: 4 mg (4 mL oral solution) PO BID</li> </ul> Body weight ≥ 40 kg: 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	<b>AS, PsA, RA</b> 11 mg PO QD	11 mg/day
<b>Very High Potency Topical Corticosteroids</b>		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	<b>AD</b> Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	AD Apply topically to the affected area(s) BID	Varies
diflorasone 0.05% (Florone®, Florone E®, Maxiflor®,Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency Topical Corticosteroids		
desoximetasone 0.05% (Topicort ®) cream, ointment, gel	AD Apply topically to the affected area(s) BID	Varies
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		
Low Potency Topical Corticosteroids		
alclometasone 0.05% (Aclovate®) cream, ointment	AD Apply topically to the affected area(s) BID	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
desonide 0.05% (Desowen <sup>®</sup> ) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar <sup>®</sup> ) solution		
hydrocortisone 2.5% (Hytone <sup>®</sup> ) cream, ointment		
Other Classes of Agents		
tacrolimus (Protopic <sup>®</sup> ), pimecrolimus (Elidel <sup>®</sup> )	<b>AD</b> Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa <sup>®</sup> (crisaborole)	<b>AD</b> Apply to the affected areas BID	Varies

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*\*Off-label*

#### *Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to upadacitinib or any of the excipients in Rinvoq/Rinvoq LQ
- Boxed warning(s): serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis

#### *Appendix D: General Information*

- Definition of MTX or DMARD Failure
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
  - Reduction in joint pain/swelling/tenderness
  - Improvement in ESR/CRP levels
  - Improvements in activities of daily living
- TNF blockers:

- Etanercept (Enbrel<sup>®</sup>), adalimumab (Humira<sup>®</sup>) and its biosimilars, infliximab (Remicade<sup>®</sup>) and its biosimilars (Avsola<sup>™</sup>, Renflexis<sup>™</sup>, Inflectra<sup>®</sup>), certolizumab pegol (Cimzia<sup>®</sup>), and golimumab (Simponi<sup>®</sup>, Simponi Aria<sup>®</sup>).

*Appendix E: The 2010 ACR Classification Criteria for RA*

Add score of categories A through D; a score of  $\geq 6$  out of 10 is needed for classification of a patient as having definite RA.

<b>A</b>	<b>Joint involvement</b>	<b>Score</b>
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
<b>B</b>	<b>Serology (at least one test result is needed for classification)</b>	
	Negative rheumatoid factor (RF) <i>and</i> negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF <i>or</i> low positive ACPA <i>* Low: <math>&lt; 3 \times</math> upper limit of normal</i>	2
	High positive RF <i>or</i> high positive ACPA <i>* High: <math>\geq 3 \times</math> upper limit of normal</i>	3
<b>C</b>	<b>Acute phase reactants (at least one test result is needed for classification)</b>	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or abnormal ESR	1
<b>D</b>	<b>Duration of symptoms</b>	
	< 6 weeks	0
	$\geq 6$ weeks	1

*Appendix F: Clinical Disease Activity Index (CDAI) Score*

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

<b>CDAI Score</b>	<b>Disease state interpretation</b>
$\leq 2.8$	Remission
$> 2.8$ to $\leq 10$	Low disease activity
$> 10$ to $\leq 22$	Moderate disease activity
$> 22$	High disease activity

*Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score*

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
$\leq 3$	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
$> 12$	High disease activity

*Appendix H: Mayo Score or Modified Mayo Score*

- Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

Score	Decoding
0 – 2	Remission
3 – 5	Mild activity
6 – 10	Moderate activity
$>10$	Severe activity

- Modified Mayo Score: developed from the full Mayo score and evaluates ulcerative colitis stage, based on three parameters: stool frequency, rectal bleeding, and endoscopic evaluation. The modified Mayo Score gives a maximum overall score of 9. The FDA currently accepts the modified Mayo Score for the assessment of disease activity in pivotal UC clinical trials.

*Appendix I: Medical Justification*

- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn's disease:
  - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
  - High-risk factors for intestinal complications may include:
    - Initial extensive ileal, ileocolonic, or proximal GI involvement
    - Initial extensive perianal/severe rectal disease
    - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
    - Deep ulcerations
    - Penetrating, structuring or stenosis disease and/or phenotype
    - Intestinal obstruction or abscess

*Appendix J: Polyarticular Juvenile Idiopathic Arthritis Disease Activity*

According to 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis, disease activity (moderate/high and low) as defined by the clinical Juvenile Disease Activity score based on 10 joints (cJADAS-10) is provided as a general parameter and should be interpreted within the clinical context.

The cJADAS10 is a continuous disease activity score specific to JIA and consisting of the following three parameters totaling a maximum of 30 points:

- Physician's global assessment of disease activity measured on a 0-10 visual analog scale (VAS), where 0 = no activity and 10 = maximum activity;
- Parent global assessment of well-being measured on a 0-10 VAS, where 0 = very well and 10 = very poor;

- Count of joints with active disease to a maximum count of 10 active joints\*

\*ACR definition of active joint: presence of swelling (not due to currently inactive synovitis or to bony enlargement) or, if swelling is not present, limitation of motion accompanied by pain, tenderness, or both

cJADAS-10	Disease state interpretation
≤ 1	Inactive disease
1.1 to 2.5	Low disease activity
2.51 to 8.5	Moderate disease activity
> 8.5	High disease activity

## V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Upadacitinib (Rinvoq)	AS, nr-axSpA, RA	15 mg PO QD	15 mg/day
	AD	<u>Age ≥ 12 years and ≥ 40 kg but &lt; 65 years:</u> 15 mg PO QD; if an adequate response is not achieved, consider increasing the dosage to 30 mg PO QD  <u>Age ≥ 65 years:</u> 15 mg PO QD	<u>Age ≥ 12 years and ≥ 40 kg but &lt; 65 years:</u> 30 mg/day  <u>Age ≥ 65 years:</u> 15 mg/day
	UC	<u>Induction:</u> 45 mg PO Q for 8 weeks  <u>Maintenance:</u> 15 mg PO QD. A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.	30 mg/day
	CD	<u>Induction:</u> 45 mg PO Q for 12 weeks  <u>Maintenance:</u> 15 mg PO QD. A dosage of 30 mg PO QD may be considered for patients with refractory, severe, or extensive disease.	30 mg/day
	PsA	<u>Age ≥ 18 years:</u> 15 mg PO QD  <u>Age ≥ 2 years but &lt; 18 years:</u> Weight ≥ 30 kg: 15 mg PO QD	15 mg/day
	pJIA	<u>Age ≥ 2 years:</u> Weight ≥ 30 kg: 15 mg PO QD	15 mg/day
Upadacitinib (Rinvoq LQ)	PsA	<u>Age ≥ 2 years but &lt; 18 years:</u> <ul style="list-style-type: none"> <li>Weight 10 kg to &lt; 20 kg: 3 mg (3 mL oral solution) PO BID</li> <li>Weight 20 kg to &lt; 30 kg: 4 mg (4 mL oral solution) PO BID</li> </ul>	12 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		<ul style="list-style-type: none"> <li>Weight <math>\geq</math> 30 kg: 6 mg (6 mL oral solution) PO BID</li> </ul>	
	pJIA	<u>Age <math>\geq</math> 2 years:</u> <ul style="list-style-type: none"> <li>Weight 10 kg to &lt; 20 kg: 3 mg (3 mL oral solution) PO BID</li> <li>Weight 20 kg to &lt; 30 kg: 4 mg (4 mL oral solution) PO BID</li> <li>Weight <math>\geq</math> 30 kg: 6 mg (6 mL oral solution) PO BID</li> </ul>	12 mg/day

## VI. Product Availability

Drug Name	Availability
Upadacitinib (Rinvoq)	Tablets, extended-release: 15 mg, 30 mg, 45 mg
Upadacitinib (Rinvoq LQ)	Oral solution: 1 mg/mL

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