STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UPADACITINIB	RINVOQ	45955		GPI-10 (6660307200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #3.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has at least TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - Rinvoq will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other JAK inhibitors (e.g., topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication

   If yes, continue to #4.
   If no, continue to #6.

4. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and switching to the requested drug
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

5. Does the patient have a trial of or contraindication to **ONE** of the following?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol, halobetasol propionate)
   - Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
   - Topical PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]
   - Topical JAK inhibitor [e.g., Opzelura (ruxolitinib)]
   - Phototherapy

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve 45mg for 8 weeks with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve 15mg and 30mg for 4 months with a quantity limit of #1 per day. (Please enter start date of 2 days before the end date of the first approval).**

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to ONE conventional agent (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve 45mg for 12 weeks with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve 15mg and 30mg for 3 months with a quantity limit of #1 per day. (Please enter start date of 2 days before the end date of the first approval).**

   If no, continue to #8.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

   If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Cimzia [certolizumab])
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient was previously stable on another biologic (e.g., Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
    - The patient has C-reactive protein (CRP) levels above the upper limit of normal
    - The patient has sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve 15mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: type of joint condition)
   2. Psoriatic arthritis (PsA: type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor)
   3. You have tried or have a contraindication (harmful for) to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (skin doctor)
   3. You have tried or have a contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

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INITIAL CRITERIA (CONTINUED)

D. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You have at least TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
   4. You had a trial of or contraindication (harmful for) to ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)
   5. You will NOT use Rinvoq concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication
   6. You meet ONE of the following:
      a. You were previously on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and switching to the requested drug
      b. You have atopic dermatitis involving at least 10% of body surface area (BSA)
      c. You have atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc.)

E. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

F. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   3. You had a trial of or contraindication (harmful for) to ONE standard therapy, such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

G. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
   4. You had an inadequate response (drug did not work) or intolerance (side effect) to one or more tumor necrosis factor (TNF) blockers (such as Humira [adalimumab], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm], Enbrel [etanercept])

H. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had an inadequate response (drug did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blockers (such as Cimzia [certolizumab])
   4. You had a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug: such as ibuprofen, naproxen, meloxicam)
   5. You meet ONE of the following:
      a. You have previously on another biologic (such as Cimzia [certolizumab], Cosentyx [secukinumab]) and switching to the requested drug
      b. You have C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      c. You have sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UPADACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) OR psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - Rinvoq will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or **OTHER** JAK inhibitors (e.g., topical Opzelura [ruxolitinib], **XELJANZ [TOFACITINIB]**) for **ANY INDICATION**

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **30mg: #1 per day.**

   If no, continue to #5.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve 15mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe atopic dermatitis (a type of skin condition)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Ankylosing spondylitis (AS: a type of joint condition)
      7. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)

   B. **If you have moderate to severe rheumatoid arthritis or psoriatic arthritis, renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
      1. You have shown improvement while on therapy
      2. You will NOT use Rinvoq concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) for atopic dermatitis or other Janus kinase (JAK) inhibitors (such as topical Opzelura [ruxolitinib], Xeljanz [tofacitinib]) for any indication

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

D. **If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES

- Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 08/19
Client Approval: 08/23
P&T Approval: 07/23