STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	39768		GPI-10 (6660306510)	

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 at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), 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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
     - **5mg: #2 per day.**
     - **11mg: #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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
     - **5mg: #2 per day.**
     - **11mg: #1 per day.**

     If no, continue to #3.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

3. 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, diclofenac, etc.)
   - The patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira [adalimumab], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
     - **5mg: #2 per day.**
     - **11mg: #1 per day.**

     If no, continue to #4.

4. 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 by 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])
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months for ALL strengths by GPID or GPI-14 as follows:**
     - **5mg and 10mg: #2 per day.**
     - **11mg and 22mg: #1 per day.**

     If no, continue to #5.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - 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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
     - **5mg: #2 per day.**
     - **1mg/mL: #10mL per day.**

     If no, do not approve.

     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 **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

     A. You have ONE of the following diagnoses:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Psoriatic arthritis (PsA: a type of skin and joint condition)
        3. Ankylosing spondylitis (AS: a type of joint condition)
        4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
        5. Polyarticular course juvenile idiopathic arthritis (pcJIA: 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 (a type of immune system doctor)
        3. You had a trial of or contraindication (harmful for) to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), 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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

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INITIAL CRITERIA (CONTINUED)

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 (a type of skin doctor)
   3. You had a trial of or 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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

D. **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 (a 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, diclofenac)
   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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

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 (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 polyarticular course juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 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 a trial of or 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], Enbrel [etanercept], Amjevita [adalimumab-atto], Cyltezo [adalimumab-adbm])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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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TOFACITINIB

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 for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of ankylosing spondylitis (AS) **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 for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **11mg: #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 for ALL strengths by GPID or GPI-14 as follows:**
   - **5mg and 10mg: #2 per day.**
   - **11mg and 22mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) 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 for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **5mg: #2 per day.**
   - **1mg/mL: #10mL per day.**

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

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

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 **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis, psoriatic arthritis, or polyarticular course juvenile idiopathic 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 ankylosing spondylitis, 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 Xeljanz/Xeljanz XR.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc.; January 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 11/12
Client Approval: 07/23
P&T Approval: 04/22