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 given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **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

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

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   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 given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

3. 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 given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agents, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a previous trial of or contraindication to the following tumor necrosis factor blocker (TNF): Humira

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

   APPROVAL TEXT: Renewal requires a diagnosis of moderate to severe ulcerative colitis.

   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: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

   B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
      1. You are 18 years of age or older
      2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
      3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   (Initial denial text continued on next page)

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following tumor necrosis factor blocker (TNF), unless there is a medical reason why you cannot (contraindication): Humira

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.

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:**
   - **Xeljanz 5mg: #2 per day**
   - **Xeljanz XR 11mg: #1 per day**

   If no, continue to #2.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

2. 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:**
   - **Xeljanz 5mg and 10mg: #2 per day.**
   - **Xeljanz 11mg and 22mg: #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 **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: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract
   B. **If you have moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA), 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

   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. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 11/12
Client Approval: 02/20
P&T Approval: 01/20