HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

TOFACITINIB (XELJANZ, XELJANZ XR)

Generic	Brand	HICL	GCN	Exception/Other
TOFACITINIB	XELJANZ, XELJANZ XR	39768		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of moderate to severe rheumatoid arthritis (RA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial or contraindication to methotrexate **OR** a previous trial with a biologic agent approved for RA (e.g., Xeljanz, Enbrel, Humira)

   If yes, continue to #4.
   If no, continue to #2.

2. Is the request for a patient with a diagnosis of psoriatic arthritis (PsA) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with **ONE** of the following:
     - o At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - o Biologic agent approved for PsA (e.g., Xeljanz, Enbrel, Humira)

   If yes, continue to #4.
   If no, continue to #3.

CONTINUED ON NEXT PAGE

TOFACITINIB (XELJANZ, XELJANZ XR)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a patient with a diagnosis of moderate to severe ulcerative colitis (UC) and does the request meet **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a gastroenterologist
   - Trial with a biologic agent approved for UC (e.g., Xeljanz, Humira, Simponi) **OR** a trial with at least two of the following conventional therapies:
     - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
     - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
     - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (if diagnosis is not met): Per your health plan's Tofacitinib (Xeljanz, Xeljanz XR) guideline, this medication is only covered for moderate to severe Rheumatoid Arthritis, Psoriatic Arthritis, or moderate to severe Ulcerative Colitis. Your physician did not indicate that you are being treated for one of these conditions and therefore your request was not approved.

   DENIAL TEXT (RA): Per your health plan's Tofacitinib (Xeljanz, Xeljanz XR) guideline, this medication is only covered for moderate to severe Rheumatoid Arthritis (RA) when you meet all of the following conditions:
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist
   - Trial or contraindication to methotrexate or a trial with a biologic agent approved for RA (e.g., Xeljanz, Enbrel, Humira), which also require prior authorization

   Your physician did not indicate **[specific criteria not met]**, and therefore your request was not approved.

   DENIAL TEXT (PsA): Per your health plan's Tofacitinib (Xeljanz, Xeljanz XR) guideline, this medication is only covered for Psoriatic Arthritis (PsA) when you meet all of the following conditions:
   - Patient is 18 years of age or older
   - Prescribed by (or in consultation with) a rheumatologist or dermatologist
   - Trial with one of the following:
     - At least one oral disease-modifying antirheumatic drug (DMARD) such as: methotrexate, leflunomide, or sulfasalazine
     - Biologic agent approved for PsA (e.g., Xeljanz, Enbrel, Humira), which also require prior authorization

   Your physician did not indicate **[specific criteria not met]**, and therefore your request was not approved.
   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

TOFACITINIB (XELJANZ, XELJANZ XR)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (UC): Per your health plan's Tofacitinib (Xeljanz, Xeljanz XR) guideline, this medication is only covered for moderate to severe Ulcerative Colitis (UC) when you meet all of the following conditions:

- Patient is 18 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist
- Trial with a biologic agent approved for UC (e.g., Xeljanz, Humira), Simponi), which also require prior authorization, or a trial with at least two of the following conventional therapies:
  - Corticosteroids (such as prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (such as sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants/Immunomodulators (such as 6-mercaptopurine, azathioprine, methotrexate)

Your physician did not indicate **[specific criteria not met]**, and therefore your request was not approved.

4. **Approve for 12 months up to 13 fills as follows:**
   - **For RA or PsA, please approve by GPID the 5 mg and 11 mg XR strengths.**
   - **For UC, please approve by GPID the 5 mg and 10 mg strengths.**

   (Xeljanz is hard-coded with a quantity of two tablets per day for Xeljanz 5mg and Xeljanz 10 mg and one tablet per day for Xeljanz XR 11 mg.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved for a quantity of _____ tablet(s) per 30-day supply for a 12-month period.

CONTINUED ON NEXT PAGE

TOFACITINIB (XELJANZ, XELJANZ XR)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the request meet **ALL** of the following criteria?
   - Prescribed for rheumatoid arthritis, psoriatic arthritis, or ulcerative colitis
   - Prescribed by (or in consultation with) a dermatologist, gastroenterologist or rheumatologist
   - Documentation that the patient experienced improvement while on therapy

   If yes, **approve for 12 months up to 13 fills as follows:**
   - **For RA or PsA, please approve by GPID the 5 mg and 11 mg XR strengths.**
   - **For UC, please approve by GPID the 5 mg and 10 mg strengths.**

   (Xeljanz is hard-coded with a quantity of two tablets per day for Xeljanz 5mg and Xeljanz 10 mg and one tablet per day for Xeljanz XR 11 mg.) Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for _____ has been approved for a quantity of _____ tablet(s) per 30-day supply for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Tofacitinib (Xeljanz, Xeljanz XR) guideline, authorization for renewal requires that you meet **ALL** of the following conditions:
   - Prescribed for rheumatoid arthritis, psoriatic arthritis or ulcerative colitis
   - Prescribed by (or in consultation with) a dermatologist, gastroenterologist or rheumatologist
   - Documentation that the patient experienced improvement while on therapy

   Your physician did not indicate that **[specific criteria not met]**, and therefore your request was not approved.

CONTINUED ON NEXT PAGE

HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

TOFACITINIB (XELJANZ, XELJANZ XR)

RATIONALE
Ensure appropriate use of Xeljanz and Xeljanz XR are consistent with the FDA approved indications.

FDA APPROVED INDICATIONS
Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).

XELJANZ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

Limitations of Use: Use of XELJANZ Xeljanz XR in combination with biological DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer; May 2018.
- FDA News Release. US Food and Drug Administration. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm327152.htm
- [Accessed 11/12/12].
- American College of Rheumatology Committee to Reevaluate Improvement Criteria. A proposed revision to the ACR20: the hybrid measure of American College of Rheumatology response. Arthritis Rheum 2007;57:193-202
- Sokka T. Radiographic scoring in rheumatoid arthritis. Bulletin of the NYU Hospital for Joint Diseases 2008; 66:166-168.
- Kyttaris, VC. Kinase inhibitors: a new class of antirheumatic drugs. Drug Design, Development and Therapy 2012:6 245–250.
- McInnes IB, Schett G. The pathogenesis of rheumatoid arthritis. N Engl J Med. 2011; 365:2205–19.
- Van Vollenhoven RF, Fleischmann R, Cohen S, et al. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. N Engl J Med 2012; 367:508-19.

Created: 11/27/12
Effective: 05/01/19 Client Approval: 04/10/19 P&T Approval: 06/04/18