STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

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

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

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

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INITIAL CRITERIA (CONTINUED)

3. 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

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
   - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
   - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

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

5. 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)

   If yes, continue to #6.
   If no, continue to #7.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet ONE of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
     - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
     - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

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

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 therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine)

     If yes, continue to #8.
     If no, continue to #9.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

8. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, **approve for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
     - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
     - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 3 weeks AFTER the END date of the first approval).**

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

9. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) 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 dermatologist
   - The patient has psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine

     If yes, continue to #10.
     If no, continue to #11.

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INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    - The patient is pregnant, breastfeeding, or trying to become pregnant
    - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), 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 by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

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

11. 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 a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam)

      If yes, continue to #12.
      If no, do not approve.
      DENIAL TEXT: See the initial denial text at the end of the guideline.

12. Does the patient meet **ONE** of the following criteria?
    - The patient was previously stable on another biologic (e.g., Cosentyx [secukinumab], Taltz [ixekizumab]) and is 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 for a total of 6 months. Please enter two authorizations by HICL or GPI-10 as follows:**
      - **<u>FIRST APPROVAL:</u> Approve for 1 month with a quantity limit of #3 kits.**
      - **<u>SECOND APPROVAL:</u> Approve for 5 months with a quantity limit of #1 kit per 28 days (Enter a start date that is 1 week AFTER the END date of the first approval).**

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

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CERTOLIZUMAB PEGOL

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 **CERTOLIZUMAB PEGOL (Cimzia)** 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 plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. 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 (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to at least 3 months of 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 meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      c. You have tried a tumor necrosis factor (TNF) inhibitor (such as Enbrel [etanercept], Humira [adalimumab]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

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CERTOLIZUMAB PEGOL

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 meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), 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 (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

E. **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 meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You have psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You had a trial of or contraindication (harmful for) to ONE or more forms of standard therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

G. **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 a trial of or contraindication (harmful for) to an NSAID (non-steroidal anti-inflammatory drug such as (e.g., ibuprofen, naproxen, meloxicam)
   4. You have ONE of the following criteria:
      a. You were previously stable on another biologic (e.g., Cosentyx [secukinumab], Taltz [ixekizumab]) and you are 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)

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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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **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, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

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

3. Does the patient have a diagnosis of 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, continue to #4.
   If no, continue to #5.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib IR or XR), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

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

5. 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) while on therapy

     If yes, continue to #6.
     If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib IR or XR), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

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

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have 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) while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ONE** of the following criteria?
   - The patient is pregnant, breastfeeding, or trying to become pregnant
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

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

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

10. Does the patient meet **ONE** of the following criteria?
    - The patient is pregnant, breastfeeding, or trying to become pregnant
    - The patient had a trial of or contraindication to TWO of the following preferred agents: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

      If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

      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 **CERTOLIZUMAB PEGOL (Cimzia)** 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 plaque psoriasis (PsO: a type of skin condition)
         5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
         6. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
      B. **If you have moderate to severe rheumatoid 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
         2. You meet ONE of the following:
            a. You are pregnant, breastfeeding, or trying to become pregnant
            b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate release or extended release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
            c. You have tried a tumor necrosis factor (TNF) inhibitor (such as Enbrel [etanercept], Humira [adalimumab]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

C. **If you have 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
   2. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Xeljanz (tofacitinib immediate release or extended release), Otezla (apremilast), Tremfya (guselkumab), Rinvoq (upadacitinib), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

D. **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) while on therapy
   2. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Xeljanz (tofacitinib immediate release or extended release), Rinvoq (upadacitinib), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

E. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy
   2. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to TWO of the following preferred medications: Humira (adalimumab), Stelara (ustekinumab), Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)

F. **If you have moderate to Crohn's disease, renewal also requires:**
   1. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

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RENEWAL CRITERIA (CONTINUED)

G. **If you have 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) while on therapy

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.

RATIONALE

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

REFERENCES

- Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23

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