

For adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation.

# The first and only therapy of its kind

for adults with nr-axSpA\*

CIMZIA.com/nraxspa

\*CIMZIA is an anti-tumor necrosis factor (TNF) biologic.



#### Indication

CIMZIA° is indicated to treat active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation.

#### **Important Safety Information**

CIMZIA can lower the ability of your immune system to fight infections. Some people who received CIMZIA have developed serious infections, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some of these serious infections have caused hospitalization and death.

Please see pages 10-11 for additional Important Safety Information and the accompanying full prescribing information, including Medication Guide.

# What is nr-axSpA?

Non-radiographic axial spondyloarthritis, or nr-axSpA (pronounced N-R-Ax-Spa), is a chronic inflammatory condition. It's characterized by active inflammation of the spine and sacroiliac (SI) joints, which are the joints that connect the lower spine and pelvis.

Nearly 1.7 million individuals in the US live with nr-axSpA

Nr-axSpA belongs to the axial spondyloarthritis (axSpA) family of inflammatory conditions. These conditions affect the spine and SI joints, but signs and symptoms can occur in other parts of the body. Ankylosing spondylitis (AS) is another condition classified in the axSpA family.

## axSpA

## nr-axSpA

Not visible on x-ray

AS

Visible on x-ray

nr	<b>Non-radiographic</b> No visible damage on x-rays
ax	Axial The part of the skeleton that includes the spine and SI joints
SpA	Spondyloarthritis A family of chronic inflammatory conditions

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#### **Important Safety Information**

Patients 65 years of age or older, patients with other long-term medical conditions, or patients taking certain other drugs that affect the immune system, such as corticosteroids or methotrexate, may be at a greater risk of infection.

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# Not all back pain is the same

Because back pain is common, many people attribute the symptoms of nr-axSpA to mechanical conditions in the structure of the back (eg, muscle strain, slipped disc, or pinched nerve). However, since the pain from nr-axSpA is caused by inflammation, it should be treated differently.

# Signs of inflammatory back pain related to nr-axSpA



PAIN THAT LASTS 3 MONTHS OR LONGER



PAIN THAT GOES AWAY WITH EXERCISE & ACTIVITY



PAIN WHILE SLEEPING



AGE OF ONSET <45 YEARS

### Additional signs and symptoms

- · stiffness, especially in the morning
- · reduced mobility
- limitations at work and home
- fatigue

Some people with nr-axSpA can experience symptoms that are more widespread, such as swelling around the joints, diarrhea, abdominal pain, and sensitivity to light.

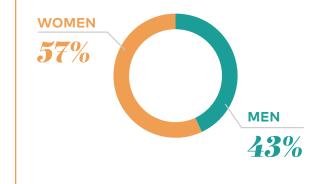
# You're too busy for a misdiagnosis

Canceled plans, trouble going to work, and unfinished jobs around the house—these are a few ways inflammatory back pain and decreased mobility could be impacting your life. Finding the right treatment is important—not only to help improve the condition, but also your overall quality of life.

## Nr-axSpA in women

Women, over half of the nr-axSpA population, may experience symptoms differently than men. Women tend to have pain that is more widespread, which can result in a diagnostic delay longer than that for men.





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## It's time for answers

Chronic pain is making it difficult to live life the way you'd like, but no one can pinpoint why. It's understandable if you've felt frustrated.

A lack of disease awareness for nr-axSpA can lead to a delay in diagnosis. It takes an average of 5-8 years and visits to multiple specialists before the condition is finally identified. However, doctors who are familiar with nr-axSpA know to look beyond the x-ray for indications of inflammation. If the signs are there, take extra care to address them with your rheumatologist so you can work together for an accurate diagnosis.

The bottom line: Understanding the condition can bring you closer to finding a treatment that works for you.



# **Confidence in diagnosis**

Since nr-axSpA is often misdiagnosed, a rheumatologist may be the best specialist to evaluate you for underlying inflammation. As part of this process, your rheumatologist will ask you questions and perform a series of tests that may include, but are not limited to:

Evaluation of medical history, including family history

Blood tests to check for inflammation and certain genetic markers

Imaging of SI joints, which could include x-ray and/or MRI

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#### **Important Safety Information**

For people receiving TNF blockers, including CIMZIA, the chances of getting lymphoma or other cancers may increase. Some children, teenagers, and young adults who received TNF blockers, including CIMZIA, have developed lymphoma and other certain types of rare cancers, some of which have caused death. These cancers are not usually seen in this age group. CIMZIA is not for use in children. People with inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, especially those with very active disease, may be more likely to get lymphoma.

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# Treating more than the symptoms

In people with nr-axSpA, pain relievers may provide temporary relief but do not address the underlying cause of the disease, which is inflammation. Proven to improve symptoms and disease activity over time, a biologic treatment may be a more appropriate option.

#### **1** WHAT IS A BIOLOGIC?

Biologics are structurally complex drugs that are made by or from living cells. They are used to treat a variety of diseases, including autoimmune diseases like nr-axSpA. CIMZIA®, a treatment for people with active nr-axSpA, is in the biologic category of anti-TNF.

#### WHAT IS TNF?

TNF (tumor necrosis factor) is a substance the body makes as part of the natural immune response. TNF signals other immune cells to begin fighting infection and disease in the body.

#### 3 WHY IS TOO MUCH TNF A PROBLEM?

In people with nr-axSpA, the body can make too much TNF, causing immune cells to attack healthy tissue. This leads to inflammation and the symptoms you may be experiencing.

#### **4** HOW CAN CIMZIA HELP YOU?

By working to block the extra signals to immune cells, CIMZIA helps reduce inflammation that leads to stiffness and back pain.

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# The first and only therapy of its kind for nr-axSpA\*

\*CIMZIA is an anti-tumor necrosis factor (TNF) biologic.

In a clinical study, CIMZIA° (certolizumab pegol) demonstrated rapid and long-lasting reductions in disease activity and spinal pain.

# Disease activity improved

IN ABOUT HALF OF PATIENTS IN 52 WEEKS & SOME AS FAST AS 2 WEEKS† LESS PAIN
AT WEEK 12 THAN
PLACEBO-TREATED
PATIENTS

CIMZIA may be able to help you get back to many of the things that matter, with fewer interruptions from symptoms.

\*47% of CIMZIA patients at 52 weeks vs. 7% of placebo patients; 21% of CIMZIA patients at 2 weeks vs. 1% of placebo patients.

Individual results may vary. Always follow the advice of your healthcare provider when using CIMZIA.

#### **Important Safety Information**

CIMZIA can lower your ability to fight infections, including tuberculosis (TB). Serious and sometimes fatal events can occur, such as infections, cancer in children and adults, heart failure, nervous system disorders, liver or blood problems, and allergic reactions. Before starting CIMZIA, your doctor should test you for TB and assess your risk of infections, including fungal infections and hepatitis B. Ask your doctor if you have been to a region where certain fungal infections are common.

Tell your doctor if you are prone to infections or develop symptoms such as fever, fatigue, cough, or sores. You should not start CIMZIA if you have an infection. These are not all the side effects associated with CIMZIA. Be sure to discuss all potential side effects with your doctor.

The most common side effects of CIMZIA include upper respiratory infections (flu, cold), rash, and urinary tract infections (bladder infections).

Please see pages 10-11 for additional Important Safety Information and the accompanying full prescribing information, including Medication Guide.

# Important Safety Information you should know about CIMZIA° (certolizumab pegol)

What is the most important information I should know about CIMZIA?

#### CIMZIA may cause serious side effects, including:

- CIMZIA is a prescription medicine called a Tumor Necrosis Factor (TNF)
  blocker that can lower the ability of your immune system to fight infections.
  Some people who received CIMZIA have developed serious infections,
  including tuberculosis (TB) and infections caused by viruses, fungi, or
  bacteria that have spread throughout the body. Some of these serious
  infections have caused hospitalization and death.
  - $\bullet$  Your healthcare provider should test you for TB before starting CIMZIA.
  - Your healthcare provider should monitor you closely for signs and symptoms of TB during treatment with CIMZIA.

#### Before starting CIMZIA, tell your healthcare provider if you:

•think you have an infection or have symptoms of an infection such as:

o muscle aches

o weight loss

o shortness of breath

o feeling very tired

o diarrhea or stomach pain

- o fever, sweat, or chills
- o cough
- o blood in phlegm
- o warm, red, or painful skin or sores on your body
- o burning when you urinate or urinate more often than normal
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV-1 or a weak immune system. People with these conditions have a higher chance for infections.
- have tuberculosis (TB), or have been in close contact with someone with TB
- were born in, live, have lived, or traveled to certain countries where there is more risk for getting TB. Ask your healthcare provider if you are not sure.
- live, have lived, or traveled to certain parts of the country (such as
  the Ohio and Mississippi River valleys and the Southwest) where
  there is an increased risk for getting certain kinds of fungal infections
  (histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis,
  blastomycosis, and pneumocystosis). These infections may develop or
  become more severe if you receive CIMZIA. Ask your healthcare provider
  if you do not know if you have lived in an area where these infections are
  common.
- · have or have had hepatitis B
- use the medicine Kineret<sup>®</sup> (anakinra), Orencia<sup>®</sup> (abatacept), Rituxan<sup>®</sup> (rituximab), or Tysabri<sup>®</sup> (natalizumab)

**Stop using CIMZIA, and tell your healthcare provider right away** if you have any of the symptoms of an infection listed above.

#### Cancer.

- For people who receive TNF blockers, including CIMZIA, the chances of getting certain types of cancers may increase.
- Some children, teenagers, and young adults who received TNF blockers, including CIMZIA, have developed lymphoma and other certain types of rare cancers, some of which have caused death. These cancers are not usually seen in this age group. CIMZIA is not for use in children.
- People with inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, especially those with very active disease, may be more likely to get lymphoma.
- Some people who receive TNF blockers, including CIMZIA, have developed a rare type of cancer which may cause death, called hepatosplenic T-cell lymphoma. Most of these people were male teenagers and young adult males with Crohn's disease or ulcerative colitis. Also, most of these people had been treated with both a TNF blocker and another medicine called IMURAN' (azathioprine) or PURINETHOL' (6-mercaptopurine, 6-MP).
- Some people who receive CIMZIA have developed certain types of skin cancer. Tell your healthcare provider if you develop any changes in the appearance of your skin, including growths on your skin, during or after treatment with CIMZIA. You should see your healthcare provider periodically during treatment for skin examinations, especially if you have a history of skin cancer.

#### What is CIMZIA?

CIMZIA is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used in adults to:

- Lessen the signs and symptoms of moderately to severely active Crohn's disease (CD) in adults who have not been helped enough by usual treatments
- · Treat moderately to severely active rheumatoid arthritis (RA)
- Treat active psoriatic arthritis (PsA)
- Treat active ankylosing spondylitis (AS)
- Treat active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation
- Treat moderate to severe plaque psoriasis (PsO) in adults who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills)

It is not known if CIMZIA is safe and effective in children.

### Before receiving CIMZIA, tell your healthcare provider about all of your medical conditions, including if you:

- · have an infection
- · have or have had lymphoma or any other type of cancer
- · have or had congestive heart failure
- have or have had seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis or Guillain-Barre syndrome.
- are scheduled to receive a vaccine. Do not receive a live vaccine while receiving CIMZIA.
- are allergic to certolizumab pegol or any of the ingredients in CIMZIA. See the Medication Guide for a complete list of the ingredients in CIMZIA.
- are pregnant or plan to become pregnant. You and your doctor should decide
  if you should continue to take CIMZIA while you are pregnant. It is not known
  if CIMZIA will harm your unborn baby. Pregnancy Registry: If you become
  pregnant during treatment with CIMZIA, talk to your healthcare provider
  about registering in the pregnancy exposure registry for CIMZIA. You can
  enroll in this registry by calling 1-877-311-8972. The purpose of this registry is
  to collect information about the safety of CIMZIA during pregnancy.
- are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby during treatment with CIMZIA.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

#### How will I receive CIMZIA?

CIMZIA comes as a lyophilized powder or a solution in a prefilled syringe for injection. If your healthcare provider prescribes the CIMZIA powder, CIMZIA should be injected by a healthcare provider. If your healthcare provider prescribes the prefilled syringe, you will be trained on how to inject CIMZIA. See the booklet called "Instructions for Use" packaged in your CIMZIA prefilled syringe kit on how to inject CIMZIA the right way. Do not give yourself an injection of CIMZIA unless you have been shown by your healthcare provider, or they can train someone you know to help you with your injection. CIMZIA is given by an injection under the skin. Your healthcare provider will tell you how much and how often to inject CIMZIA. Do not use more CIMZIA or inject more often than prescribed.

## What are the possible side effects of CIMZIA? CIMZIA can cause serious side effects, including:

CIMZIA can cause serious side effects, including:
 See "What is the most important information I should know about CIMZIA?"

- Heart failure including new heart failure or worsening of heart failure you already have. Symptoms include shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Allergic reactions. Signs of an allergic reaction include a skin rash; swelling or
  itching of the face, tongue, lips, or throat; or trouble breathing.
   The plastic needle shield inside the removable cap of the prefilled syringe
  contains natural rubber and may cause an allergic reaction if you are sensitive
  to latex.
- Hepatitis B virus reactivation in people who carry the virus in their blood. In some cases, people who received CIMZIA have died because of the hepatitis B virus being reactivated. Your healthcare provider should monitor you carefully before and during treatment with CIMZIA to see if you carry the hepatitis B virus in your blood. Tell your healthcare provider if you have any of the following symptoms:
  - o feel unwell
- o skin or eyes look yellow o poor appetite or vomiting
- o tiredness (fatigue)
- o pain on the right side of
- your stomach (abdomen)
- New or worsening nervous system problems, such as multiple sclerosis (MS), Guillain-Barre syndrome, seizures, or inflammation of the nerves of the eyes.
   Symptoms may include:
  - o dizziness
- o numbness or tingling
- o problems with your vision o weakness in your arms or legs
- Blood problems. Your body may not make enough of the blood cells that help
  fight infections or help stop bleeding. Symptoms include a fever that does
  not go away, bruising or bleeding very easily, or looking very pale. Tell your
  healthcare provider right away if you have any bruising, bleeding or a fever
  that does not go away.
- Immune reactions including a lupus-like syndrome. Symptoms include shortness of breath, joint pain, or a rash on your cheeks or arms that worsens with sun exposure.

Call your healthcare provider right away if you have any serious side effects listed above.

The most common side effects of CIMZIA include upper respiratory infections (flu, cold), rash, and urinary tract infections (bladder infections).

These are not all of the possible side effects of CIMZIA. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Medication Guide for CIMZIA and discuss it with your healthcare provider.

# Getting started with CIMZIA® (certolizumab pegol)

**CIMZIA** is available in 2 formulations. You and your doctor will determine which treatment choice is right for you based on your ability to self-inject or your access to a trained caregiver.

#### **PREFILLED SYRINGE**

A healthcare provider will train you or a loved one on the proper way to inject CIMZIA under the skin so you can self-inject at home.



The prefilled syringe is designed for comfort and control in partnership with



GOOD GRIPS®

OXO, Good Grips®, and the associated logos are registered trademarks of Helen of Troy Limited and are used under license.

Please read the prefilled syringe "Instructions for Use" booklet in your CIMZIA kit. Watch the video instructions at www.cimzia.com.

#### IN-OFFICE INJECTION

A powder that is prepared and injected by a healthcare professional at your doctor's office.



#### **Important Safety Information**

Allergic reactions may occur. Signs of an allergic reaction include a skin rash; swelling or itching of the face, tongue, lips or throat; or trouble breathing. The plastic needle shield inside the removable cap of the prefilled syringe contains natural rubber and may cause an allergic reaction if you are sensitive to latex.

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# Dosing for nr-axSpA

A starting dose is recommended for treatment with CIMZIA° followed by a maintenance dose.

#### STARTER DOSE

First 3 doses:

DAY O

400 mg 2 injections of 200 mg/mL **DAY 14** 

**400 mg**2 injections
of 200 mg/mL

**DAY 28** 

**400 mg** 2 injections of 200 mg/mL

#### MAINTENANCE DOSE

After completing the initial starter doses, you will continue with maintenance dosing.

#### **EVERY 2 WEEKS**

200 mg 1 injection of 200 mg/mL **EVERY 4 WEEKS** 

400 mg 2 injections of 200 mg/mL

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# \$0 out-of-pocket,\*nurse support, and more

Count on us for the tools and support you need to help you stay on treatment.



cimplicity. Two ways to treat.
Two ways to save.

#### PREFILLED SYRINGE -

#### The CIMplicity Savings Program

Eligible patients may receive help covering out-of-pocket costs.\*



ENROLL at 1-866-4CIMZIA (866-424-6942). Have your insurance card handy.



RECEIVE savings card by mail in a few days.



ACTIVATE your savings card by phone.

#### IN-OFFICE INJECTION -

#### CIMZIA Co-Pay Savings Program

Eligible patients may be able to get help covering out-of-pocket costs.\*



Member of doctor's staff can enroll you.



Staff submits claims on your behalf.

The associated Co-Pay Savings Program is valid for out-of-pocket expenses for CIMZIA® (certolizumab pegol) per current Program rules. Offer is not valid for any other products or other outof-pocket costs, even if those costs are associated with the injection of a dose of CIMZIA. Payment is subject to claim verification and submission of an Explanation of Benefits. After the claim is processed, the card will be funded. Card can only be used at the issuing healthcare facility to offset the qualifying out-of-pocket amount owed by the patient.

Use of this Co-Pay Savings Program permits your healthcare provider or pharmacy to share limited information with certain UCB vendors to determine if additional resources may be available to you and to act on your behalf to initiate any processes that may be necessary to access these resources.

 ${}^\star \text{Eligibility: Available to individuals with commercial prescription insurance coverage for CIMZIA. Not}$ valid for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, similar federal- or state-funded programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), or where otherwise prohibited by law. Product dispensed pursuant to program rules and federal and state laws. Claims should not be submitted to any public payor (ie, Medicare, Medicaid, Medigap, TRICARE, VA, and DoD) for reimbursement. The maximum annual benefit amount is \$15,000 per calendar year. The parties reserve the right to amend or end this program at any time without notice.

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# CIMplicity Nurse Support

We know the first weeks of treatment can be the hardest. Our CIMplicity Nursing program will provide you with supplemental CIMZIA education, including dosing and injection training, as well as related disease state information and support services to reinforce the education provided by your physician to help you on your CIMZIA treatment journey.

- Answer questions about your CIMZIA treatment
- Provide training using the prefilled syringe
- Help you achieve your treatment goals
- Provide info on available resources and support

Speak with a CIMplicity Nurse today to learn about all our CIMplicity services.



Text CONNECT to 87522

Call 1-844-UCBNurse (1-844-822-6877)

The CIMplicity Nursing program does not provide you with medical advice and does not replace the care of your healthcare provider.



#### SYRINGE DISPOSAL

Get a free container delivered to your home for a safe way to properly store and dispose of your used CIMZIA prefilled syringes.



#### MEDICATION REMINDERS

Sign up and receive your choice of a text, phone call, or email letting you know that it's time for your next CIMZIA treatment.

If you do not have insurance, other financial assistance may be available, Call ucbCARES® at 1-844-599-CARE (2273) for more information.

<sup>&</sup>lt;sup>†</sup>This program does not replace the care and medical advice of your doctor. CIMplicity Nurses do not give medical advice and will direct you to share your treatment-related questions with your doctor.



# FIRST & ONLY

therapy of its kind for nr-axSpA\*

> \*CIMZIA is an antitumor necrosis factor (TNF) biologic.

# Disease activity improved

IN ABOUT HALF OF PATIENTS IN 52 WEEKS & SOME AS FAST AS 2 WEEKS'

- Understand your nr-axSpA diagnosis
- Find relief in knowing how CIMZIA may be able to help
- Feel supported every step of the way

Talk to your rheumatologist and sign up at CIMZIA.com/praxspa for more information.

<sup>†</sup>47% of CIMZIA patients at 52 weeks vs. 7% of placebo patients; 21% of CIMZIA patients at 2 weeks vs. 1% of placebo patients.

Individual results may vary. Always follow the advice of your healthcare provider when using CIMZIA.

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