MEET ELIZA

Eliza lost response on her anti-TNF therapy.

She's ready for a new plan.

CIMZIA® (certolizumab pegol)

Treatment she can plan on.

Clinical response was 63% (n=215) for CIMZIA patients with moderate-to-severe Crohn's disease vs. 36% (n=210) for placebo patients, based on a 26-week study in which patients received 400 mg at 0, 2, and 4 weeks (during 6-week loading dose period), followed by 400 mg every 4 weeks.[1] As with any treatment, the decision to continue or discontinue therapy is between the physician and the patient.

CD

Indication

CIMZIA is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Important Safety Information

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

Please see additional Important Safety Information on pages 8–9.
Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

Eliza's clinical and treatment history

CD

Diagnosis	• Diagnosed at 26 years of age with moderate-to-severe CD
Treatment history	• Over the first 3 years of treatment, was on an antidiarrheal, steriod pulses with taper, azathioprine, and an anti-TNF
Symptom history	• Began losing response to treatment ▪ ≥7 liquid or soft stools per day ▪ Moderate abdominal pain and cramping weekly ▪ Poor well-being: moderate fatigue, malnutrition, bloody stool, and inflammation ▪ Symptoms worse in evening, impacting her busy family life and work ▪ Experiencing some lower back pain, severe at times
Eliza's goal	• Hoping her next treatment will relieve some of her increasing symptoms

Eliza was diagnosed with CD 3 years ago at age 26

The patient presented in this case example represents a patient profile and not an actual patient.

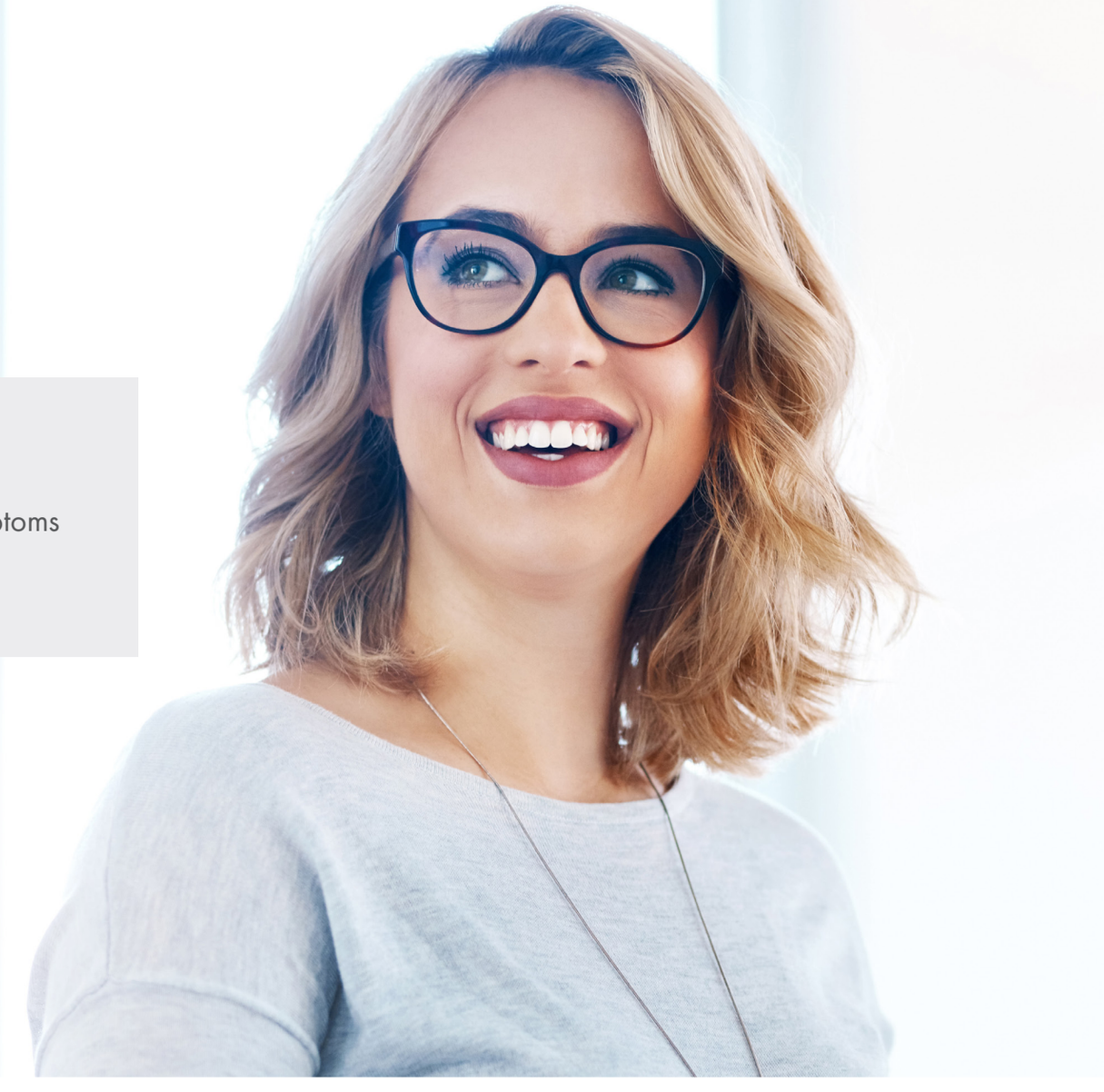
Important Safety Information

Cases of lymphoma and other malignancies have been observed among patients receiving TNF blockers, including children, adolescents, and young adults. Acute and chronic cases of leukemia have also been reported. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA. Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-antagonists, including CIMZIA. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

Eliza’s therapeutic goals

For supporting her plans for the future



Eliza’s therapeutic goals

- Rapid relief and durable improvement in signs and symptoms
- Ability to return to active lifestyle and plan for the future

Important Safety Information

Patients treated with CIMZIA are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g. corticosteroids or methotrexate) may be at a greater risk of infection.

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

Eliza started CIMZIA® (certolizumab pegol) **with the approved and recommended loading dose**

CD

PRECiSE 2 open-label loading dose

64% of all patients (n=668) achieved a clinical response by week 6[2]

- All patients received CIMZIA 400 mg at weeks 0, 2, and 4[2]
- Clinical response was defined as a ≥100-point reduction in CDAI[2]
- These results should be interpreted with caution as there is a limited ability to evaluate treatment effect due to the open-label, single-arm study design that lacked a placebo control or active comparator during induction
- Patients were evaluated for clinical response at week 6, and responders were then randomized to CIMZIA treatment or placebo

PRECiSE 2 Study Design[2]

Six hundred sixty-eight patients (adults with CD ≥3 months) received CIMZIA 400-mg loading dose subcutaneously at weeks 0, 2, and 4 in an open-label induction phase. Starting at week 8, week 6 responders received CIMZIA 400 mg every 4 weeks (n=215) or placebo (n=210). Primary end point: clinical response at week 26 in patients with baseline C-reactive protein (CRP) ≥10 mg/L.

Important Safety Information

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers.

Anaphylaxis or serious allergic reactions may occur. Some of these reactions occurred after the first administration of CIMZIA. Hypersensitivity reactions have been reported rarely following CIMZIA administration. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

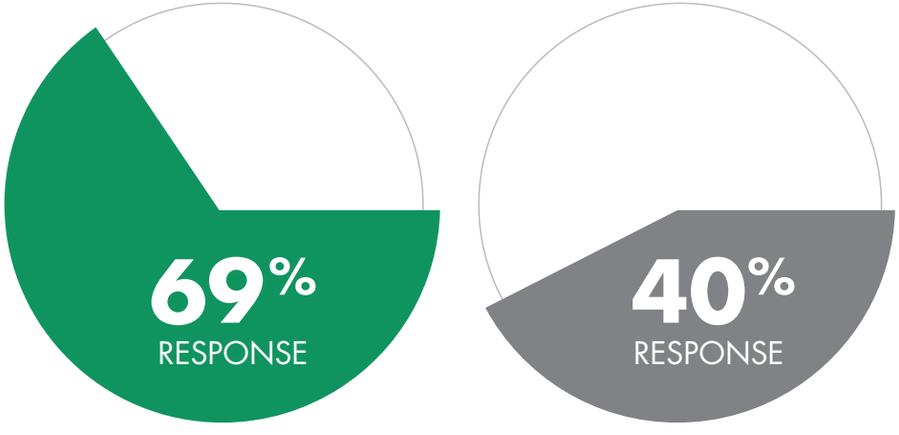
Eliza's previous anti-TNF treatment didn't go as planned

CD

CIMZIA® (certolizumab pegol) produced significant clinical response* at week 26 among week 6 responders in the overall population of PRECiSE 2[2†]

- 63% of CIMZIA patients (n=215) vs. 36% of placebo patients (n=210; *P*<0.001)

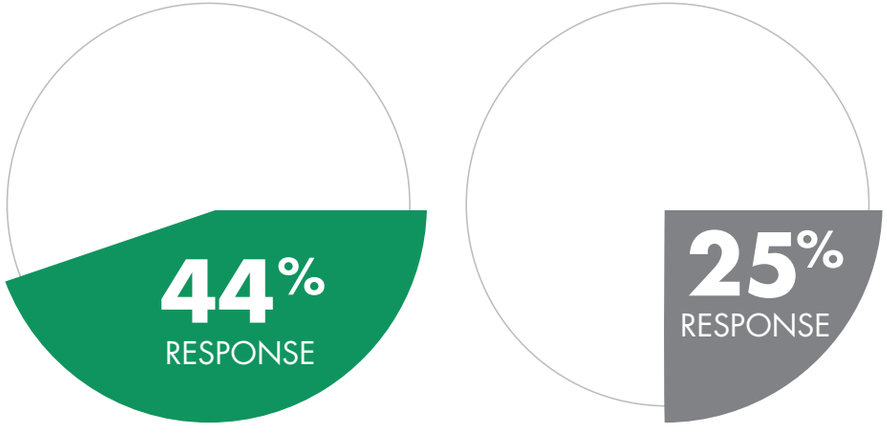
BIO-NAÏVE[2]



n=163 n=159

***P*<0.001**

BIO-EXPERIENCED[2]



n=52 n=51

***P*=0.02**

CIMZIA 400 mg Q4W
Placebo

- Patients with severe hypersensitivity or anaphylactic reaction and patients who were primary failures to previous anti-TNF therapy were excluded from PRECiSE 2

*Clinical response was defined as a ≥100-point reduction in Crohn's Disease Activitiy Index (CDAI) score.
†All patients received a loading dose of CIMZIA 400 mg at weeks 0, 2, and 4.

Important Safety Information

Concurrent administration of CIMZIA with certain biological DMARDs, including anakinra, abatacept and rituximab, is not recommended due to an increased risk of serious infections.

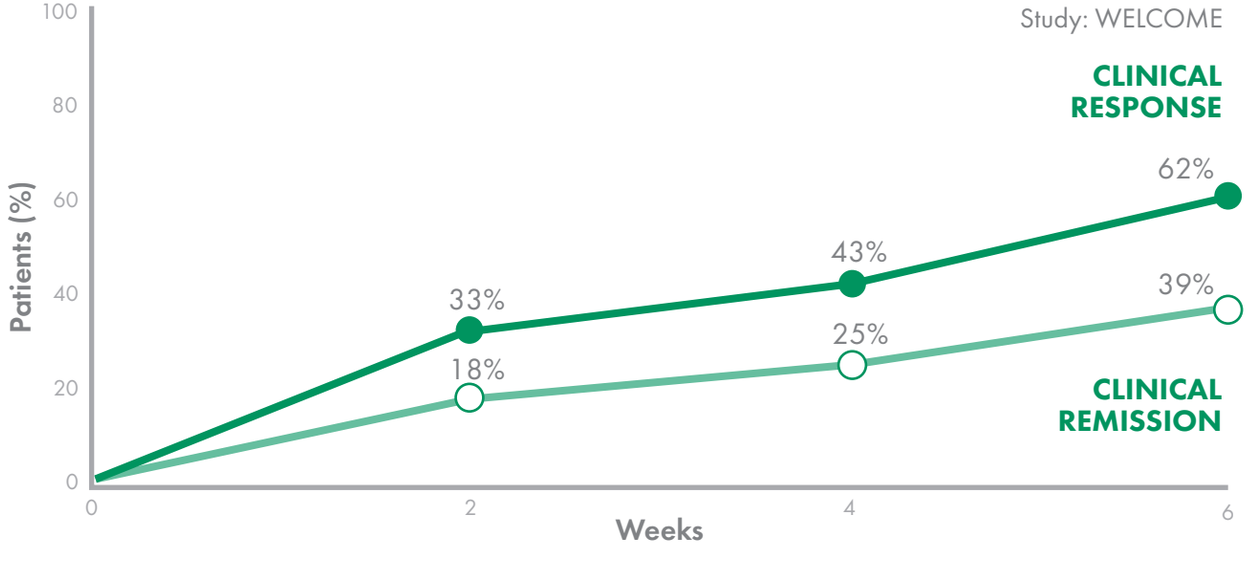
Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

CIMZIA may offer a clinical response by week 6 in patients who lost response and/or experienced hypersensitivity to infliximab[3]

CD

WELCOME open-label study—clinical response and remission over time

CLINICAL RESPONSE AND CLINICAL REMISSION WITH CIMZIA THROUGH WEEK 6 IN PATIENTS WHO LOST RESPONSE AND/OR EXPERIENCED HYPERSENSITIVITY TO INFLIXIMAB (n=539)[3*†]



- In WELCOME, all patients who had a clinical response (≥100-point decrease in CDAI score) to CIMZIA had a previous clinical response to anti-TNF therapy but were no longer adequately responding and/or had developed hypersensitivity[3]
- The results of WELCOME should be interpreted with caution as there is a limited ability to evaluate treatment effect due to the open-label, single-arm study design that lacked a placebo control or active comparator during induction

*Clinical response defined as decrease from baseline in CDAI score ≥100. Primary end point was clinical response at week 6. The same patients may not have responded at each time point.

†Clinical remission defined as CDAI score ≤150.

WELCOME Study Design[3]

Five hundred thirty-nine patients with moderate-to-severe CD (adults with loss of response [lack of improvement/worsening of clinical symptoms after 2 consecutive infusions of at least 5 mg/kg with a maximum interval of 8 weeks evaluated within 2–6 weeks after last infusion] and/or hypersensitivity [acute infusion reactions within 2 hours of infusion or delayed infusion reactions within 1–14 days after infusion] to infliximab) received CIMZIA 400-mg loading dose subcutaneously at weeks 0, 2, and 4 in an open-label induction phase. Those in clinical response at week 6 were randomized to CIMZIA 400 mg every 2 or every 4 weeks through week 24. The primary end point was response at week 6. Secondary end points included remission at week 6.

Important Safety Information

In pre-marketing controlled trials of all patient populations combined, the most common adverse reactions (≥8%) were upper respiratory infections (18%), rash (9%) and urinary tract infections (8%).

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

She only needs to administer CIMZIA every 4 weeks after the initial loading period[1]

Use the Starter Kit containing the CIMZIA loading dose

The loading dose has been shown to quickly lead to increased plasma levels.

Patients and their caregivers can be trained to administer CIMZIA Prefilled Syringe in their own home.

The Starter Kit contains everything patients need to get started on therapy.

Prefilled syringe designed for comfort and control in partnership with OXO GOOD GRIPS

LOADING DOSE*

2 INJECTIONS
400 mg
(2x200 mg/mL)
AT WEEK 0

2 INJECTIONS
400 mg
(2x200 mg/mL)
AT WEEK 2

2 INJECTIONS
400 mg
(2x200 mg/mL)
AT WEEK 4

MAINTENANCE DOSE*

2 INJECTIONS
400 mg
(2x200 mg/mL)

EVERY 4 WEEKS

*For subcutaneous administration in abdomen or thigh. Please see section 2 of full Prescribing Information for additional dosing and administration information.

Important Safety Information

Anaphylaxis or serious allergic reactions may occur. Some of these reactions occurred after the first administration of CIMZIA. Hypersensitivity reactions have been reported rarely following CIMZIA administration. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

Indication

CIMZIA® (certolizumab pegol) is indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

Important Safety Information

Contraindications

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

Serious Infections

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

Malignancy

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.

- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

Heart Failure

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

Hypersensitivity

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Hepatitis B Virus Reactivation

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

Neurologic Reactions

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

Hematologic Reactions

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

Drug Interactions

- Do not use CIMZIA in combination with other biological DMARDS.

Autoimmunity

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

Immunizations

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

Adverse Reactions

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

CIMZIA® (certolizumab pegol)

Treatment she can plan on.

Rapid clinical response[2]

- CIMZIA provides rapid clinical response

Dosed every 4 weeks after the loading dose in CD[1]

Important Safety Information

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

References

1. CIMZIA® [prescribing information]. Smyrna, GA: UCB, Inc.; 2019. **2.** Schreiber S, Khaliq-Kareemi M, Lawrance IC, et al. Maintenance therapy with certolizumab pegol for Crohn's disease. *N Engl J Med*. 2007;357:239-250. **3.** Sandborn WJ, Abreu AT, D'Haens G, et al. Certolizumab pegol in patients with moderate to severe Crohn's disease and secondary failure to infliximab. *Clin Gastroenterol Hepatol*. 2010;8:688-695.

Please see additional Important Safety Information on pages 8–9. Please ask your UCB representative for the full Prescribing Information, and visit CIMZIAhcp.com.

cimzia®
(certolizumab pegol)

Inspired by **patients.**
Driven by **science.**