NC Division of Health Benefits	**Medicaid**
Outpatient Pharmacy	**Effective Date:**
Prior Approval Criteria	**Amended Date:**
Zymfentra	

Therapeutic Class Code: S2J
Therapeutic Class Description: Anti-Inflammatory Tumor Necrosis Factor Inhibitor

Medication
Zymfentra

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21

Years of Age 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination(includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in

the *Basic Medicaid Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.
***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:

https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Initial Approval Criteria for Zymfentra:

- Beneficiary must be ≥ 18 years of age

AND

- Beneficiary has documented moderate or severe ulcerative colitis (UC);

OR

- Beneficiary has documented moderate or severe Crohn's Disease (CD);

AND

- Beneficiary has received treatment with an infliximab product administered intravenously (IV) for ≥ 10 weeks and has demonstrated a clinical response to infliximab therapy (e.g., decrease in modified Mayo score, decrease in rectal bleeding, decrease in Crohn's disease activity index [CDAI] score, decrease in simplified endoscopic activity score for Crohn's disease [SES-CD]);

AND

- Beneficiary must not have hypersensitivity to any component of the product, to any infliximab product, or to any murine products;

AND

- Beneficiary has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment;

AND

- Beneficiary has been evaluated and screened for the presence of Hepatitis B (HBV) prior to initiating treatment;

AND

- Beneficiary does NOT have an active infection, including clinically-important localized infections;

AND

- Beneficiary does NOT have a history of malignancy;

AND

- Beneficiary does NOT have moderate to severe chronic obstructive pulmonary disease (COPD);

AND

- Zymfentra will not be administered concurrently with live vaccines;

AND

- Beneficiary is not on concurrent treatment with another TNF-inhibitor, interleukin (IL)-inhibitor, biologic response modifier, or other non-biologic agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, Upadacitinib, deucravacitinib).
- Initial approval shall be for 6 months.

Criteria for Subcutaneous Maintenance Therapy of Zymfentra:

Renewal criteria:

- **Beneficiary** must continue to meet the above criteria;

AND

- Beneficiary must demonstrate a clinical response to therapy;

AND

- Beneficiary has not experienced any treatment-restricting adverse effects (e.g., serious infection, sepsis, malignancy, HBV reactivation, hepatotoxicity, new or worsening congestive heart failure, significant hematologic abnormalities, neurologic reactions, lupus-like syndrome).
- Renewal approval shall be for 12 months.

References

1. Zymfentra [package insert]. Jersey City, NJ; Celltrion; October 2023.
2. Sands BE, Hanauer SB, Colombel JF, et al. P492 subcutaneous infliximab (CT-P13 SC) as maintenance therapy for ulcerative colitis: a phase 3, randomized, placebo-controlled study: results of the LIBERTY-UC study. Journal of Crohn's and Colitis. 2023;17(supp 1):i623-i624. DOI: 10.1093/ecco-jcc/jjac190.0622.
3. Colombel JF, Hanauer SB, Sandborn W, et al. DOP86 subcutaneous infliximab (CT-P13 SC) as maintenance therapy for Crohn's disease: a phase 3, randomized, placebo-controlled study (LIBERTY-CD). Journal of Crohn's and Colitis. 2023;17(supp 1):i161-i162. DOI: 10.1093/ecco-jcc/jjac190.0126.

NC Division of Health Benefits **Outpatient Pharmacy** **Prior Approval Criteria** **Zymfentra**	**Medicaid** **Effective Date:** **Amended Date:**

Criteria Change Log

xx/xx/xxxx	Criteria effective date