Instructions:

This template serves as a valuable tool for healthcare providers in formulating their responses to letters of appeal regarding product changes when prescribing ZYMFENTRATM (infliximab-dyyd). It is recommended to include certain attachments when submitting the completed letter, such as the original claim form, a copy of denial or explanation of benefits, and any other relevant supporting documents. For additional references, please reach out to the Celltrion CONNECT® Patient Support Program at 1-877-812-6662.

**The use of this template does not guarantee approval or reimbursement for the prescribed ZYMFENTRA product. Furthermore, it is not intended to replace or influence the independent medical judgment of the healthcare provider.**

**For more information about ZYMFENTRA, including boxed warning, see full Prescribing Information.**

**Sample Letter of Appeal – Product Change**

*(Healthcare Provider Letterhead)*

[Your name]

[Your address]

[Your city, state, ZIP]

[Your phone number]

[Tax ID#]

[Date]

Patient Name: [Patient Name]

Patient Date of Birth: [Patient Date of Birth]

[Name of Insurance Plan]

Member ID: [Member ID #]

Group Number: [Number]

[Address of Insurance Plan]

Claim or Explanation of Benefit #:

Re: Action Required: Request for Reconsideration for ZYMFENTRATM (infliximab-dyyb) Subcutaneous Injection [XX mg] for [Patient Name]

To whom it may concern:

My name is [Physician Name]and I am a [board-certified medical specialty] [NPI]. This letter serves as the [1st/2nd] appeal for approval of ZYMFENTRA (infliximab-dyyb) which was originally denied to [Patient Name] on [date]. I am writing this letter to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [condition], [ICD code(s)], with ZYMFENTRA, a product indicated for the treatment of [Add Indication].

In brief, treating [Patient Name]with ZYMFENTRA is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name]determined ZYMFENTRA was not covered for [Patient Name]because [reason(s) for denial]. This letter provides my clinical rationale and relevant information about the patient's medical history and treatment.

**Patient’s Clinical History**

[Must include: Patient’s clinical / medical history, diagnosis, condition, and symptoms:] [Patient Name]is [a/an] [age]-year-old [male/female]patient who has been diagnosed with [condition][ICD-10-code(s)]as of [date of diagnosis]. [He/she] has been in my care since [date].

[Include any additional considerations here:]

My rationale for prescribing ZYMFENTRA is based on [include a brief disease course of patient, including history of disease, laboratory results, symptoms, and previous treatments (including names, dosages, frequency, and length). If the patient has discontinued treatment, please include information on the reasons for such discontinuation, such as inability to tolerate a previous treatment, lack of response and or side effects. include medical reasoning for choosing to bypass any alternative medications covered by the health plan such as COVID-19 risk exposure due to multiple infusions, patient may not be able to comply with labeled multiple dosing requirements of covered products over an extended period of time, and treatment guidelines such as NPF/AAD, ACR, and NICE].

[Please exercise your medical judgment and discretion when providing diagnosis and characterization of the patient’s medical condition].

**Treatment Plan**

On October 23, 2023, the FDA approved ZYMFENTRA for the treatment of [Indication]. [Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of] ZYMFENTRA. [Consider mentioning experts in the field who also support the treatment].

**Summary**

Based on the patient’s condition and medical history, as well as my experience treating patients with [diagnosis], I believe treatment with ZYMFENTRA is warranted, appropriate, and medically necessary in this case. The accompanying package insert provides the approved clinical information for ZYMFENTRA. I have attached relevant lab test analyses and medical records to support my decision.

I am requesting an immediate and expedited review of this appeal, and the enclosed documents and supporting evidence by my office and by a board certified and specialty matched physician who can render a decision based upon the standards of care outlined above. If you have any further questions about this matter, please contact me at [Physician Phone Number], via e-mail at [Physician Email], or by fax at [Provider Fax Number]. I look forward to receiving your timely response and approval of this claim.

Once approved for ZYMFENTRA, I will discontinue the treatment/prescription of [alternate BRAND (generic) name].

If you do not feel that the information provided has established medical necessity, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an applicable medical specialty.

Sincerely,

[Physician Name] [Physician Signature]

[Physician Address]

[Physician Phone Number]

**Enclosures**

[List enclosures, which may include medical records/clinical notes for ZYMFENTRA, ZYMFENTRA Prescribing Information, letter of medical necessity and other supporting documentation]

[Include Indication and Important Safety Information]

[Include full Prescribing Information, including Patient Information]

**References**

[Include other relevant references and publications regarding prescribed medicine]

[Copy of patient denial letter]

[Clinical progress notes] [Patient’s lab results]

[Documentation of Hospitalization/ Emergency Room visits and/or unscheduled office visits]

[List of medications provided including, dosages, dates used, and if samples were given]

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