Instructions:

This template is intended for use in response to a healthcare provider's request for a sample resource that can assist them in addressing a patient's health benefit request and the medical necessity of ZYMFENTRATM (infliximab-dyyd). When submitting the letter, it is recommended to include the following attachments: the original claim form, a copy of the denial or explanation of benefits, and any other supplementary supporting documents. For further 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 Medical Necessity**

*(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: Letter of Medical Necessity – Coverage Request 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]. I am writing on behalf of my patient [Patient Name] to document the medical necessity of ZYMFENTRA (infliximab-dyyb) Subcutaneous Injection [XX mg] for my patient, who is currently a member of [Health Plan Name]. This letter provides information about the patient’s medical history and diagnosis and a statement summarizing my treatment rationale.

The prescription is for ZYMFENTRA, which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)].Therefore, I am requesting that [Health Plan Name]remove any medical policy or guideline requirements in this case so that ZYMFENTRA can be made available to my patient as a covered medication.

**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:]

* [Previous treatments including drug names, duration of treatment(s), responses to those treatments (see table below)]
* [Acute and chronic complications]
* [Treatment plan: expected duration of treatment or number of injections requesting medical exception for]
* [Why you believe it is Medically Necessary for the Patient to receive ZYMFENTRA]
* [Supporting Letters from other Specialist(s) that is currently or has previously provided Care to the Patient]

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 (see table below). You may also want to include medical reasoning for choosing to bypass any alternative medications covered by the health plan such as COVID-19 risk exposure, or other infectious diseases, 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 any treatment guidelines].

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

|  |  |  |
| --- | --- | --- |
| **Past Treatment(s)** | **Start/Stop Dates** | **Reason(s) for Discontinuing** |
| [Drug name] | [MM/YY] – [MM/YY] | [Please list reasons] |
| [Drug name] | [MM/YY] – [MM/YY] | [Please list reasons] |

**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 my experience treating patients with [diagnosis], I have concluded that ZYMFENTRA is medically appropriate in this case. I further attest [include physician expectations regarding clinical outcomes for patient].

I am requesting an immediate and expedited review of this request 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 questions, please contact me at [Physician Phone Number]for a peer-to-peer discussion. I would be pleased to speak to you in more detail about why a ZYMFENTRA formulary exception is necessary for [Patient Name]’s treatment of [diagnosis].

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 appropriate medical specialty.

I look forward to receiving your timely response and approval of ZYMFENTRA.

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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