

SAMPLE LETTER OF APPEAL: FORMULARY EXCEPTION

<Date>

<Payer Name>

<Payer Address>

Attn: <Appeals Department>

Re: <Patient Name>

<Policy ID/Group Number>

<Date of Service>

<Disputed Amount>

To Whom It May Concern:

I am writing to request that a formulary exception be granted for <Patient Name> for the administration of TAKHZYRO® (lanadelumab-flyo). TAKHZYRO was approved by the U.S. Food & Drug Administration (FDA) in August 2018 and is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older. In February 2023, the U.S. FDA approved the expanded use of TAKHZYRO® for prophylaxis to prevent attacks of hereditary angioedema (HAE) in pediatric patients 2 to <12 years of age. <Payer Name> does not include TAKHZYRO on the approved formulary list.

<Patient Name> has been diagnosed with HAE and I believe that TAKHZYRO is the appropriate treatment. It is imperative that a formulary exception be made for my patient. In my clinical judgment, treatment with TAKHZYRO is medically necessary. <Provide clinical justification for the use of TAKHZYRO>.

I have enclosed additional documentation that supports treatment with TAKHZYRO. In the best interest of my patient, I appreciate your immediate review and ask that a formulary exception be granted. If you have any further questions, please feel free to call me at <Physician Telephone #> to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

<Physician Name>

<Enclosures: formulary exception form (if required, available on the payer's website), original claim form and subsequent denial/EOB (if relevant), patient medical history, full Prescribing Information, additional supporting documents>