Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

April 2020

Subject: Self-administration of XOLAIR (omalizumab) Pre-Filled Syringe for asthma during the COVID-19 pandemic

Dear Health Care Provider:

In consultation with the US Food and Drug Administration (FDA), Genentech is issuing this letter to provide you with safety information regarding temporary self-administration of XOLAIR in pre-filled syringe (PFS) during the COVID-19 pandemic.

The current US label states that XOLAIR (omalizumab) should be administered in a healthcare setting by healthcare providers who are prepared to manage anaphylaxis given the risk of severe hypersensitivity reactions associated with XOLAIR. At this time, self-administration of XOLAIR is not currently approved in the US. However, administration in a healthcare setting may be a challenge in the context of the current COVID-19 pandemic. For patients with moderate to severe asthma, identified by the US Centers for Disease Control and Prevention as a high-risk population for severe illness due to COVID-19 infection, the risks of interrupted XOLAIR asthma therapy and potential viral exposure are both major concerns.

While administration of XOLAIR in a healthcare setting remains the preferred mode of administration where possible, there may be cases where the Health Care Provider (HCP) determines that self-administration of XOLAIR PFS by a patient or lay caregiver (e.g. to a pediatric patient) may be temporarily warranted in the context of local COVID- 19-related guidelines and restrictions, and individual patient factors.

Prescriber Action

Genentech recommends that HCPs consider the following risk-based patient selection criteria when assessing the risk-benefit of self-administration with XOLAIR PFS for individual patients:

- **No prior history of anaphylaxis related or unrelated to XOLAIR**
  - In a retrospective case-control study of patients with asthma, a history of anaphylaxis to foods, medications, or other causes was identified as a risk factor for anaphylaxis to XOLAIR (Lieberman PL et al. J Allergy Clin Immunol. 2016; Lieberman PL et al. J Allergy Clin Immunol. 2017).
- **At least 3 doses of XOLAIR have already been administered**
  - In the same case-control study, approximately 60 to 70% of cases of anaphylaxis were reported to occur within the first three doses of Xolair, with additional cases occurring sporadically beyond the third dose.

- **Ability to recognize and manage signs and symptoms of a severe hypersensitivity reaction, including anaphylaxis**
  - Assess the patient's or caregiver's understanding of the signs and symptoms of anaphylaxis and the ability to manage a severe hypersensitivity reaction. Confirm availability of self-injectable epinephrine for emergency use.
- **Ability to perform injections with XOLAIR PFS with proper technique and per the prescribed dosing regimen**
  - Provide training and assess the patient's or caregiver's ability to perform the proper technique for subcutaneous injection, properly store and dispose of the PFS, and adhere to the prescribed dose and dosing frequency. Refer to Section 2.4 of the current USPI for information on proper preparation, administration, and storage of XOLAIR PFS.

Genentech recommends that HCPs discuss individual risks and benefits of self-administration with patients prior to transitioning to self-administration.

In the event the HCP decides it is appropriate for a patient to temporarily self-administer XOLAIR PFS, please ensure the specialty pharmacy is aware of this request for the patient.

Reporting Adverse Events and Product Complaints

Health Care Providers should report any adverse events suspected to be associated with the use of XOLAIR to Genentech at 1-888-835-2555.

Health Care Providers should report any product complaint suspected to be associated with the use of XOLAIR to Genentech at (800) 334-0290.

Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

Should you have any questions about the information in this letter or the safe and effective use of XOLAIR, please feel free to contact us at: Genentech Medical Information/Communications Department at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of XOLAIR. Please refer to the enclosed full prescribing information (and medication guide, or any other approved patient information).

Sincerely,

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs