From:	Michele Puyear
To:	Pharmacy Services
Cc:	Michelle Duke
Subject:	Xolair comments for Jan 27th DUR meeting
Date:	Friday, January 21, 2022 9:00:22 AM
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Hello,

I am reaching out to provide comments on Xolair for the Jan 27th DUR meeting.

I wanted to make you aware that Xolair was FDA approved for an additional indication in December 2020. It is now indicated for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. As this indication isn't currently listed in the Prior Authorization I would like to request the committee consider including the nasal polyps indication within the approval criteria for Xolair.

Here is an overview of dosing, administration, and adverse events for nasal polyps. I'm also attaching the current PI which details the important safety information.

Dosing and administration for adult patients with nasal polyps (Table 3 is directly from the PI)

A patient's pretreatment serum total IgE level (IU/mL) and body weight (lb or kg) are used to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose.

Table 3. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with Nasal Polyps

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

*Dosing frequency:

Subcutaneous doses to be administered every 4 weeks
Subcutaneous doses to be administered every 2 weeks

- Administer XOLAIR 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks
- Determine dose (mg) and dosing frequency both by serum total IgE level (IU/mL) measured before the start of treatment and by body weight (lb or kg)
- For adult patients with both asthma and nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, the retesting of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
    - Interruptions lasting less than one year: Dose based on serum IgE levels obtained at the initial dose determination
    - Interruptions lasting one year or more: Retest total serum IgE levels for dose determination
- Periodically reassess the need for continued therapy based on the patient's disease severity and level of symptom control

ADVERSE REACTIONS

Nasal Polyps: The most common adverse reactions (≥3% incidence in XOLAIR-treated patients and more frequent than placebo) included: headache (8.1%), injection site reaction (5.2%), arthralgia (3.0%), upper abdominal pain (3.0%), and dizziness (3.0%).

Thank you for your consideration.
Michele

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