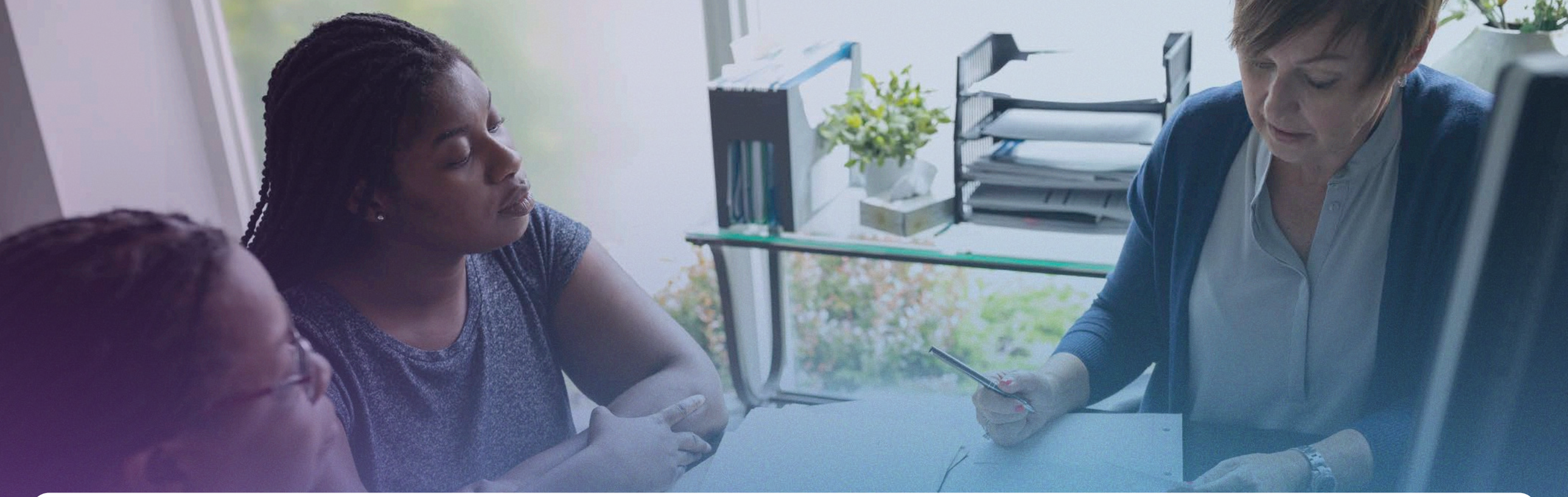


CONSIDERATIONS FOR INCORPORATING XOLAIR FOR IgE-MEDIATED FOOD ALLERGY INTO YOUR PRACTICE WORKFLOW

Xolair® Omalizumab

FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

INDICATION

XOLAIR® (omalizumab) is indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

XOLAIR is to be used in conjunction with food allergen avoidance.

Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Genentech
A Member of the Roche Group

NOVARTIS

XOLAIR FOR IgE-MEDIATED FOOD ALLERGY

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

XOLAIR is indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.[1]

Limitations of use:
XOLAIR is to be used in conjunction with food allergen avoidance.

With the introduction of this type of treatment, practices may need to adjust their logistics and workflow processes.

This comprehensive guide reviews some tips and considerations to keep in mind once your organization has decided to begin prescribing XOLAIR for IgE-mediated food allergy.

YOUR DEDICATED XOLAIR TEAM

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Our team of Specialists are here to help your patients and practice.

Meet your team

- **Genentech Therapeutic Area Managers (TAMs)/Novartis Therapeutic Area Specialists (TASs)/Therapeutic Area Associates (TAAs)**
  Provide education on the clinical efficacy, safety, dosing, and the science behind XOLAIR. If samples are needed, these representatives can provide information on how to access them. They may also provide basic information about access, financial assistance and My Patient Solutions® for Health Care Practices, our online patient management tool.

TAMs, TASs and TAAs are the "sales reps" for XOLAIR.

- **Genentech Field Reimbursement Managers**
  Provide support with understanding regional/local payer coverage, reimbursement and access policies.
- **Genentech Clinical Education Managers**
  Provide patient education about XOLAIR. They do not provide medical advice to patients. If patients have questions about their health or treatment, they are encouraged to contact their healthcare provider.
- **XOLAIR Access Solutions Specialist**
  Sometimes referred to as "case managers," they can help with facilitating enrollment in XOLAIR Access Solutions, address patient-specific access questions, work with payers to conduct benefits investigations (BIs), provide resources for prior authorizations (PAs) and refer patients to appropriate financial assistance options.
- **Foundation Specialists**
  Your main point of contact at the Genentech Patient Foundation.
- **Business Engagement Managers (BEMs)**
  Your main point of contact for questions about XOLAIR discounts and rebates.

PATIENT ACCESS ROADMAP

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Once the decision has been made to prescribe XOLAIR, access must be secured. Below is an overview of what to expect.

Determine patient coverage	Secure prior authorization (PA)	Acquire XOLAIR	XOLAIR is administered	Secure reauthorization when it is time
Financial assistance options are available for eligible patients*	If a PA is denied, you can file an appeal	XOLAIR may be acquired via buy and bill or specialty pharmacy (SP)	After the first 3 injections, the physician can determine if self-injection is right for the patient[1]	The reauthorization process follows these same steps

XOLAIR Access Solutions is here to help your patients and practice after XOLAIR is prescribed. Register your practice for My Patient Solutions® for Health Care Practices to work with XOLAIR Access Solutions when it's convenient for you.

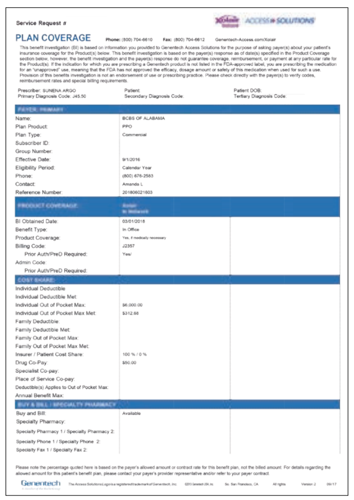
*Each option has its own eligibility criteria that must be met for patients to receive assistance.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

DETERMINING PATIENTS' COVERAGE

XOLAIR Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

- Once XOLAIR has been prescribed, the first step is to check the patient's coverage through a benefits investigation (BI).
- You may perform the BI yourself, rely on the specialty pharmacy (SP) (if applicable), or **XOLAIR Access Solutions can conduct the BI**.



The results of a BI conducted by XOLAIR Access Solutions are provided to you in a BI Report, which can be viewed online via My Patient Solutions®, our online patient management tool, or faxed to your office.

Resources for BIs

Potential outcomes of a BI:

- Treatment is covered
- Prior authorization (PA) is required
- Treatment is denied

Your BI includes patient cost-sharing responsibilities (e.g., deductibles, co-pays, co-insurance). This may help you determine if financial assistance may be needed.

Find out which financial assistance options are available

Request a BI from XOLAIR Access Solutions by submitting the Prescriber Service Form and the Patient Consent Form to XOLAIR Access Solutions.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech and Novartis Pharmaceuticals Corporation make no representation or guarantee concerning coverage or reimbursement for any service or item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

RESOURCES FOR BENEFITS INVESTIGATIONS (BIs)

Xolair® Omalizumab
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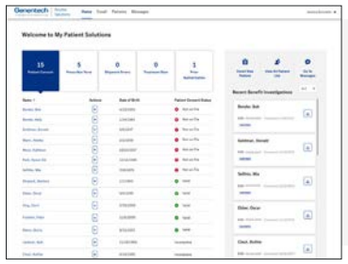
XOLAIR Bio-Advo Kit

This comprehensive guide walks you through the access and reimbursement support services, as well as financial assistance options for XOLAIR.



Learn About My Patient Solutions® for Health Care Practices

My Patient Solutions is an online tool that lets you enroll and manage your XOLAIR Access Solutions patients online.

Your XOLAIR Access Solutions Specialist can conduct the BI on behalf of your patients and practice.

Your Field Reimbursement Manager (FRM) can visit your practice to assist with patient access or provide local payer information about XOLAIR.

FINANCIAL ASSISTANCE OPTIONS

Financial assistance options may be available for your patient, no matter what type of health insurance your patient has. Click on a program name or contact your representative to learn about each of these options.

	COMMERCIAL Insurance	**PUBLIC** Insurance	**NO** Insurance
XOLAIR Co-pay Program*	✓		
Referrals to Independent Co-pay Assistance Foundations†	✓	✓	
Genentech Patient Foundation‡	✓	✓	✓

XOLAIR Access Solutions can help identify potential financial assistance options so your patient may get started on XOLAIR.

*Eligibility criteria and benefit limits apply. Not valid for patients whose prescriptions are reimbursed under any federal or state government programs to pay for their medicine and/or administration of their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay program website for the full list of Terms and Conditions.

†Independent co-pay assistance foundations have their own rules for eligibility. Genentech and Novartis Pharmaceuticals Corporation have no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help your patient. We can only refer your patient to a foundation that supports their disease state. Genentech and Novartis Pharmaceuticals Corporation do not endorse or show preference for any particular foundation. The foundations to which we refer your patient may not be the only ones that might be able to help.

‡To be eligible for free Genentech medicine from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

SECURING THE PRIOR AUTHORIZATION (PA)

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- Most health insurance plans require a PA for XOLAIR. It is important to understand your patient's health insurance plan requirements and take steps to ensure that all PA requests are complete and accurate.
- Be sure to check with the patient's payer to determine what is required and submit a PA.

- **XOLAIR Access Solutions** can help you identify the required forms and documents for your submission to the health insurance plan.

With the XOLAIR Starter Program, eligible patients taking XOLAIR may receive free medicine while awaiting a health insurance coverage determination.

Learn more

Considerations for requesting a PA

- Understand payer guidelines
- Check with the payer to determine the length of the authorization, as this can vary
- Submit all required supporting documents with the PA request
- Highlight key sections of the letter of medical necessity and documentation (e.g., test results, patient history)
- Keep complete records, including a copy of everything you send and a log of every phone call you make to the patient's health insurance plan

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech and Novartis Pharmaceuticals Corporation make no representation or guarantee concerning coverage or reimbursement for any service or item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

COMMON PA CRITERIA FOR XOLAIR FOR IgE-MEDIATED FOOD ALLERGY[2-4]

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- Patient is 1 year of age or older
- Clinical history of systemic allergic reaction to food
- Documentation of diagnostic tests (e.g., positive skin prick test, specific IgE serum levels, oral food challenge)
- Prescribed by a specialist (e.g., allergist, immunologist)
- No history of poorly controlled atopic dermatitis or asthma

Coverage policies can change, please check with the health plan directly to confirm coverage criteria for individual patients.

Diagnostic tests that may be required:

- Baseline IgE
- Skin prick test
- Specific IgE serum levels
- Oral food challenge

Payer utilization management is common for biologic drugs like XOLAIR, so denials are fairly frequent. However, denials are not the end of the road.

If a PA is denied, the health insurance plan's decision may be appealed.

Learn more about denials and appeals

Sample codes

Resources for PAs

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech and Novartis Pharmaceuticals Corporation make no representation or guarantee concerning coverage or reimbursement for any service or item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

RESOURCES FOR PAs

Xolair® Omalizumab
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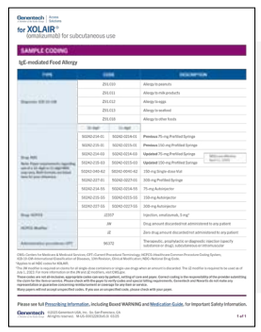
XOLAIR Bio-Advo Kit

This comprehensive guide walks you through the access and reimbursement support services, as well as financial assistance options for XOLAIR.

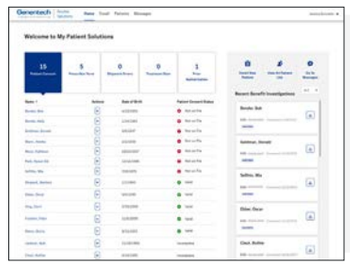


Sample Coding

A list of sample codes for XOLAIR.

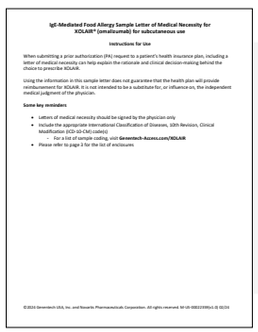
Considerations for Composing a Letter of Medical Necessity

This guide provides tips to help you draft a letter of medical necessity. A sample letter is also included for your reference.



Learn About My Patient Solutions® for Health Care Practices

My Patient Solutions is an online tool that lets you enroll and manage your XOLAIR Access Solutions patients online.



Food Allergy Sample Letter of Medical Necessity

You can use this sample letter as a template when composing a letter of medical necessity.

Your Field Reimbursement Manager can visit your practice to assist with patient access or provide local payer information about XOLAIR.

GET PATIENTS STARTED ON XOLAIR

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

XOLAIR Starter Program*

With the XOLAIR Starter Program, eligible patients taking XOLAIR may receive free medicine while awaiting an insurance coverage determination.

Eligible patients experiencing a delay in establishing health insurance coverage, of at least 5 business days, may receive one free 28-day supply of XOLAIR. If a coverage delay persists, the patient may be eligible for one 28-day refill of XOLAIR.

If you think your patient qualifies for the XOLAIR Starter Program, submit the completed Prescriber Service Form and the Patient Consent Form to XOLAIR Access Solutions.

*Subject to eligibility requirements and terms and conditions. This program is void where prohibited by law and may not be used in or by residents of restricted states, if applicable.

UNDERSTANDING DENIALS

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A prior authorization (PA) can be denied for various reasons.*

Administrative

May be due to:

- Incomplete forms
- Inaccurate information or coding
- Payers not having complete or correct codes in their systems

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If the denial was made due to a practice error, it can usually be resolved without submitting an appeal (e.g., submitting corrected paperwork/additional information, making a phone call)

Policy

Occurs when the payer's policy for XOLAIR has stricter guidelines on what they will cover

---

Generally requires an appeal

Appeals will require additional documentation, such as:

- Denial letter
- Medical documentation
- Other supporting documentation
- Appeal letter

View an overview of the appeals process

View a list of NDCs and other coding information

NDC=National Drug Code.

*Check directly with the payer to verify why a denial was issued.

Appeals cannot be completed or submitted by XOLAIR Access Solutions on your behalf.

APPEALS

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If a patient's health insurance plan denies your request for prior authorization or coverage for XOLAIR, you may submit an appeal. The denial should be reviewed, along with the health insurance plan's guidelines, to determine what to include in your patient's appeal submission.

Compile	Submit	Follow up
The appeals documentation as per payer request.	The documentation prior to the payer's deadline and keep a copy for your records.	With the payer to ensure receipt of documentation and to learn the result of the appeal.

Appeals cannot be completed or submitted by XOLAIR Access Solutions on your behalf.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech and Novartis Pharmaceuticals Corporation make no representation or guarantee concerning coverage or reimbursement for any service or item.

CHECKLIST FOR APPEALS

Xolair® Omalizumab
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- ☐ Understand the reason for a denial. This can be found in the explanation of benefits (EOB) or the denial letter
- ☐ Identify the payer-specific appeals process and deadlines
- ☐ Double-check documentation to ensure it included:
  - ☐ Accurate patient information
  - ☐ Correct codes (e.g., ICD-10-CM, NDC, HCPCS)
  - ☐ Prescription information
  - ☐ Dosing information
  - ☐ Correctly completed forms, if applicable

If a documentation error was made, contact the payer to adjust the form.

Commonly requested documentation

- ☐ EOB and/or denial letter
- ☐ Medical documentation, including:
  - ☐ Patient history
  - ☐ Chart notes
  - ☐ Records of prior treatments and outcomes
  - ☐ Lab data or other test results (e.g., specific IgE serum level, total IgE serum levels)
- ☐ Other supporting documentation, including:
  - ☐ Journal articles
  - ☐ Practice guidelines
  - ☐ Compendia indications
- ☐ Appeal letter

If the denial was made due to payers not having correct codes in their systems or finalized policies, be sure to document these conversations thoroughly and follow up with the payer to prevent future denials.

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

Appeals cannot be completed or submitted by XOLAIR Access Solutions on your behalf.

RESOURCES FOR APPEALS

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

XOLAIR Bio-Advo Kit

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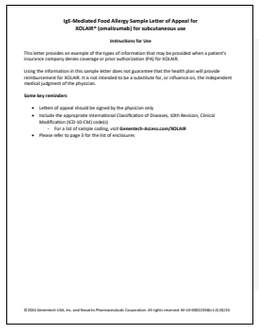

IgE-Mediated Food Allergy Sample Letter of Appeal for XOLAIR® (omalizumab) for subcutaneous use

Instructions for Use

This letter provides an example of the types of information that may be provided when a patient's insurance company denies coverage or prior authorization (PA) for XOLAIR.

Using the information in this sample letter does not guarantee that the health plan will provide reimbursement for XOLAIR. It is not intended to be a substitute for, or influence on, the independent medical judgment of the physician.

Some key reminders

- Letters of appeal should be signed by the physician only
- Include the appropriate International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code(s)
  - For a list of sample coding, visit Genentech-Access.com/XOLAIR
- Please refer to page 3 for the list of exclusions

Food Allergy Sample Appeal Letter

You can use this sample letter as a template when composing an appeal letter.

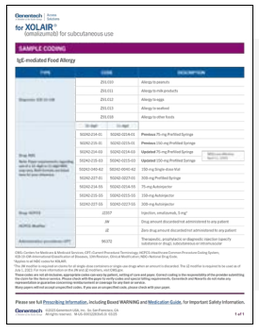

CONSIDERATIONS for Composing an Appeal Letter

Tips for drafting an Appeal Letter

Genentech

Considerations for Composing a Sample Appeal Letter

This guide provides tips to help you draft an appeal letter. A sample letter is also included for your reference.


Genentech
for XOLAIR®
(omalizumab) for subcutaneous use

SAMPLE CODING

IgE-mediated Food Allergy

Sample Coding

A list of sample codes for XOLAIR.

Appeals cannot be completed or submitted by XOLAIR Access Solutions on your behalf.

Your Field Reimbursement Manager (FRM) can visit your practice to assist with patient access or provide local payer information about XOLAIR.

XOLAIR MAY BE ACQUIRED VIA BUY AND BILL OR SPECIALTY PHARMACY (SP)

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

The decision to use buy and bill or SP is up to the individual practice and the patient's health insurance plan. XOLAIR Access Solutions can help you determine a patient's health insurance requirements.

Buy and Bill

- Practice purchases drug from authorized distributor
- Practice follows health plan's policies to determine co-pay and billing
- Practice bills health insurance for drug and administration
- Patient pays practice the out-of-pocket costs for drug and administration unless patient has co-pay assistance to cover out-of-pocket costs

My practice uses buy and bill

Specialty Pharmacy (SP)

- Provider sends prescription to the SP
- SP purchases and bills health insurance for drug
- Practice bills health insurance for administration only
- SP contacts patient to collect drug co-pay (drug cannot be shipped until the drug co-pay has been collected)

My practice uses SP

If the patient self-administers XOLAIR, it must be obtained via SP.

Genentech and Novartis Pharmaceuticals Corporation have contracted with a network of authorized specialty distributors to service practices choosing to purchase XOLAIR through the buy and bill model. Customers can purchase XOLAIR through authorized specialty distributors and wholesalers that have made a commitment to product integrity. These partners have agreed to distribute only products purchased directly from Genentech and Novartis Pharmaceuticals Corporation and not to distribute XOLAIR through secondary channels.

Genentech and Novartis Pharmaceuticals Corporation do not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

CONSIDERATIONS FOR BUY AND BILL

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Is buy and bill is right for your practice?

- Determine your mix of payers; if your patients have Medicare Fee-for-Service plans, including Medicare Part B, then you must use buy and bill or send the patient to an alternate injection center (AIC)
- Investigate the acquisition cost
- Understand your payer contracts and reimbursement process
- Check to see if the patient's health insurance plan prohibits buy and bill and/or requires the use of a specific SP
- Establish a process for the purchase, storage, administration and inventory management of XOLAIR

What should your practice know about buy and bill?

How does my office become eligible to participate in buy and bill?

There are no eligibility requirements for participating in buy and bill. The decision to use buy and bill is up to the individual practice and the patient's health insurance plan.

How do I know if my practice can use buy and bill?

Check to see if the patient's health insurance plan prohibits buy and bill and/or requires the use of a specific SP.

What is my practice responsible for?

Your practice is responsible for purchase, storage and inventory of XOLAIR.

Will my practice have any direct costs?

Your practice will incur overhead costs for the purchase, storage and inventory of XOLAIR.

What do I bill for?

Practice bills for both the injection and for the product itself.

How does this affect my Medicare patients?

If your patients have Medicare Fee-for-Service plans, then you must use buy and bill.

Genentech and Novartis Pharmaceuticals Corporation have contracted with a network of authorized specialty distributors to service practices choosing to purchase XOLAIR through the buy and bill model. Customers can purchase XOLAIR through authorized specialty distributors and wholesalers that have made a commitment to product integrity. These partners have agreed to distribute only products purchased directly from Genentech and Novartis Pharmaceuticals Corporation and not to distribute XOLAIR through secondary channels.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

STEPS FOR USING BUY AND BILL

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

1. Order XOLAIR from an authorized distributor.
2. Obtain prior authorization (PA) from the payer.
3. Collect co-pay from the patient (if applicable) and bill the health insurance plan for both XOLAIR and the administration process. Follow the health insurance plan's policies for determining the patient's co-pay and billing for treatment.
4. Administer XOLAIR after receipt of approved PA.
5. Submit the explanation of benefits (EOB) for both drug and administration to the XOLAIR Co-pay Program, if the patient is enrolled.
6. Manage inventory for XOLAIR. Your practice is responsible for inventory management. Inventory decisions should be based on individual patient and practice needs.

For a list of authorized distributors, visit Genentech-Access.com/XOLAIR.

Resources for buy and bill

Genentech and Novartis Pharmaceuticals Corporation have contracted with a network of authorized specialty distributors to service practices choosing to purchase XOLAIR through the buy and bill model. Customers can purchase XOLAIR through authorized specialty distributors and wholesalers that have made a commitment to product integrity. These partners have agreed to distribute only products purchased directly from Genentech and Novartis Pharmaceuticals Corporation and not to distribute XOLAIR through secondary channels.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

RESOURCES FOR BUY AND BILL

Xolair® Omalizumab
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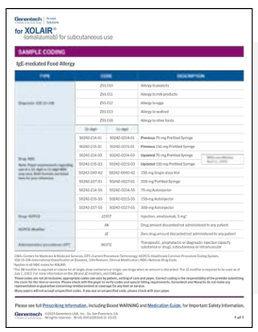
How to Obtain XOLAIR Through Buy and Bill

This guide provides helpful considerations and answers frequently asked questions about obtaining XOLAIR via buy and bill.

Authorized Distributors

A list of authorized distributors for XOLAIR.



Sample Coding

A list of sample codes for XOLAIR.

Contact your XOLAIR team to request a copy of these resources.

STEPS FOR WORKING WITH SPs

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

1. Your practice sends the prescription to the SP.
2. In most cases, the SP obtains prior authorization (PA) from the payer. Be sure to confirm any PA requirements for administering SP-acquired drugs.
3. SP coordinates shipment of the drug to the practice, alternate injection center (AIC) or the patient.
4. Practice or patient administers XOLAIR.
5. Submit the EOB for administration only to the XOLAIR Co-pay Program, if the patient is enrolled.

You can work with your preferred SP or contact XOLAIR Access Solutions to learn which SP the patient's health insurance plan requires.

What resources can an SP provide your practice?

- Reimbursement resources
- Clinical services to support patients throughout their treatment
- The ability to manage the specialty handling and shipping needs linked with many specialty therapies

Genentech and Novartis Pharmaceuticals Corporation do not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

CONSIDERATIONS FOR WORKING WITH SPs

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Be mindful of the need for coordination among the practice, patient and SP in terms of communication and scheduling

Educate patients about SP requirements around co-pays and shipping

Identify or request a point of contact at the SP

Be aware of specific health insurance plan policies and any SP mandates, including requiring the use of a specific SP

Be on the lookout for any SP communications regarding reauthorization for treatment and follow any instructions to avoid potential gaps in therapy

For patients needing financial assistance, coordination with manufacturer assistance programs may also be required.

Genentech and Novartis Pharmaceuticals Corporation do not influence or advocate the use of any one specialty distributor or specialty pharmacy. We make no representation or guarantee of service or coverage of any item.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

ADMINISTRATION CONSIDERATIONS

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The first 3 injections are administered in-office, allowing the physician and patient/caregiver to decide if self-injection is appropriate.[1]

When administering XOLAIR in your office, consider:

- Which staff members will be responsible for administering XOLAIR and ensure they are prepared to manage anaphylaxis
- Treatment and observation time
- Staff availability
- The patient's situation (e.g., distance traveled for appointments)
- How long XOLAIR will take to obtain
  - **If your practice uses buy and bill:** By ordering the product prior to use, the practice has product readily available for administration
  - **If your practice uses SP:** Designate sufficient lead time for order and delivery of the product and schedule injections around delivery schedules

Identifying patients for self-administration

Administration resources

IDENTIFYING PATIENTS FOR SELF-ADMINISTRATION[1]

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

Healthcare providers should consider known risk factors for anaphylaxis to XOLAIR and mitigation strategies when selecting patients for self-administration.

Patient-specific factors, including the following criteria, should be considered:

1. Patient should have no prior history of anaphylaxis to XOLAIR or other agents (except foods), such as drugs, biologics, etc.
2. Patient should receive at least 3 doses of XOLAIR under the guidance of a healthcare provider with no hypersensitivity reactions
3. Patient or caregiver is able to recognize symptoms of anaphylaxis
4. Patient or caregiver is able to treat anaphylaxis appropriately
5. Patient or caregiver is able to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use

Adolescents 12 years of age and older

- The XOLAIR **prefilled syringe** may be self-administered under adult supervision
- The XOLAIR **autoinjector** may be self-administered under adult supervision
  - The XOLAIR autoinjectors (all doses) are intended for use only in adults and adolescents aged 12 years and older

Pediatric patients 1 to 11 years of age

- The XOLAIR **prefilled syringe** should be administered by a caregiver
- The XOLAIR **autoinjectors** (all doses) are **not intended for use** in pediatric patients under 12 years of age

RESOURCES FOR ADMINISTRATION

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

XOLAIR Prescribing Information

XOLAIR Self-Injection Brochure (available in English or Spanish)

This brochure provides step-by-step instructions for how to administer XOLAIR.

XOLAIRHCP.com

XOLAIR Dosing Guide

Dosing and administration information for XOLAIR.

Clinical Education Managers are Genentech employees who educate about XOLAIR. They do not provide medical advice to patients. If patients have questions about their health or treatment, they are encouraged to contact their healthcare provider.

Your TAM, TAS or TAA can provide your practice with clinical information about XOLAIR dosing and administration.

CEMs can provide injection training to patients and caregivers.

XOLAIR DOSING OPTIONS AND WHOLESALE ACQUISITION COST (WAC)

Xolair® Omalizumab
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The recommended dosage for IgE-mediated food allergy is XOLAIR 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL), measured before the start of treatment, and by body weight.

XOLAIR example dosing

Example dose	75-mg PFS/autoinjector	150-mg PFS/autoinjector/vial	300-mg PFS/autoinjector
75 mg	1		
150 mg		1	
225 mg	1	1	
300 mg			1
375 mg	1		1
450 mg		1	1
525 mg	1	1	1
600 mg			2

XOLAIR WAC[5]*

75-mg PFS (26-gauge)	NDC 50242-214-01	[$XXXXXX]
AVAILABLE APRIL 11, 2025 75-mg PFS (27-gauge)	NDC 50242-214-03	
75-mg autoinjector	NDC 50242-214-55	
150-mg PFS (26-gauge)	NDC 50242-215-01	[$XXXXXX]
AVAILABLE APRIL 11, 2025 150-mg PFS (27-gauge)	NDC 50242-215-03	
150-mg autoinjector	NDC 50242-215-55	
150-mg vial	NDC 50242-040-61	
300-mg PFS	NDC 50242-227-01	[$XXXXXX]
300-mg autoinjector	NDC 50242-227-55	

Current as of [Month 2025].

NDC=National Drug Code; PFS=prefilled syringe.

*WAC is the list price for wholesalers, distributors or other direct accounts before any rebates, discounts, stocking or distribution allowances, chargebacks and/or other price concessions or fees that may be offered by Genentech. For certain products, one or more forms of price concession, in addition to a prompt pay discount, may be available on sales.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

RECERTIFICATION

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

→ When a medical treatment is authorized for a limited period of time, the health insurance plan will generally require recertification for coverage of continued treatment. Most of the recertification criteria will be similar to the original prior authorization criteria, with potentially a few additional/different criteria.[2-4]

Common recertification criteria[2-4]

Attestation of positive clinical response to therapy as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen

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Attestation that the patient will continue to maintain a food-allergen avoidance diet

If you would like XOLAIR Access Solutions to send you reminders via fax to recertify your patients for XOLAIR, you can enroll in the XOLAIR Recertification Reminder Program. To enroll, complete the XOLAIR Recertification Reminder Program Enrollment Form.

Note: If the patient's health insurance plan denies the request for recertification, an appeal may be filed.

IMPORTANT SAFETY INFORMATION

Xolair® Omalizumab
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INDICATION

XOLAIR® (omalizumab) is indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

XOLAIR is to be used in conjunction with food allergen avoidance.

Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

CONTRAINDICATIONS

XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis: Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials and in postmarketing spontaneous reports. In premarketing clinical trials in patients for a different indication, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy: Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

IMPORTANT SAFETY INFORMATION (CONT)

Xolair® Omalizumab
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WARNINGS AND PRECAUTIONS (cont)

Malignancy (cont): A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients for a different indication found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Fever, Arthralgia, and Rash: In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection: Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests: Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for IgE-mediated food allergy patients, because these levels may not reflect steady state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

IgE-Mediated Food Allergy: The most common adverse reactions (≥3% incidence in XOLAIR-treated patients) included: injection site reaction (15.5%) and pyrexia (6.4%). Safety data obtained from adults (n=3) in this trial was limited.

Injection Site Reactions: Injection site reactions occurred at a rate of 15.5% in XOLAIR-treated patients compared with 10.9% in placebo-treated patients. The types of injection site reactions included: urticaria, discomfort, erythema, pain, and rash. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.

Injection Site Reactions in Healthy Adults: In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

Cardiovascular and Cerebrovascular Events from Clinical Studies in Patients for a Different Indication: A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication to evaluate the long term safety of XOLAIR, including the risk of malignancy. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy: Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

WE ARE HERE TO HELP YOU

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We believe every patient should get the XOLAIR they have been prescribed, and we offer programs to help make this happen.

Contact us for more information.

Visit Genentech-Access.com/XOLAIR

Call (800) 704-6610

Contact your representative

References: 1. XOLAIR. Prescribing information. South San Francisco, CA: Genentech, Inc and Novartis Pharmaceuticals Corporation; 2024. **2.** UnitedHealthcare. Xolair® (omalizumab). Effective January 1, 2025. Accessed March 19, 2025. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/xolair-omalizumab.pdf **3.** Aetna. Omalizumab (Xolair). Accessed March 19, 2025. Effective May 20, 2024. https://www.aetna.com/cpb/medical/data/600_699/0670.html **4.** Blue Cross Blue Shield Blue Care of Michigan. Xolair® (omalizumab). Effective October 3, 2024. Accessed March 19, 2025. https://www.bcbsm.com/amslibs/content/dam/public/providers/documents/xolair-omalizumab-policy.pdf **5.** Data on File. Genentech Inc.

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