



# PROVIDER BULLETIN

No. 04-04

March 24, 2004

TO: Physicians Participating in Nebraska Medicaid

FROM: Bob Seiffert, Medicaid Administrator

BY: Chris Wright, M.D., F.A.A.P., Medicaid Medical Director  
Lorelee Novak, R.N., Medicaid Program Specialist – Physician Services

RE: Medicaid Coverage of Xolair®  
(Coverage Criteria, Prior Authorization and Billing Requirements)

EFFECTIVE: April 1, 2004

IgE blocker therapy such as omalizumab (Xolair® subcutaneous) is covered by Nebraska Medicaid as an alternative treatment for the management of moderate-to-severe persistent extrinsic asthma in adults and adolescents 12 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are ***inadequately*** controlled after current standard measures (including the use of medium doses of inhaled corticosteroids).

Safety and efficacy of IgE blocker therapy such as omalizumab in the management of other allergic conditions have not been established and will not be covered by Nebraska Medicaid. IgE blocker therapy will not be covered as initial therapy for allergic asthma, for non-allergic asthma, or for allergic conditions without asthma.

## COVERAGE CRITERIA

Medicaid reimbursement may be available for Xolair® for the patient who meets the following conditions:

1. Is 12 years old or older.
2. Is being followed by an asthma specialist (i.e., allergist/immunologist, pulmonologist) who has done a comprehensive evaluation, has reviewed the Medicaid coverage criteria, and has prescribed the IgE blocker therapy.

3. Has had moderate persistent or severe persistent asthma (as defined by the *National Institutes of Health's Guidelines for the Diagnosis and Management of Asthma*, July 1997) for at least one year.

Severe Persistent:

Continual symptoms  
Limited physical activity  
Frequent exacerbations  
Nighttime symptoms frequent  
FEV1 or PEF  $< \text{ or } = 60\%$  predicted  
PEF variability  $> 30\%$

Moderate Persistent:

Daily symptoms (e.g. coughing, wheezing, dyspnea)  
Daily use of inhaled short acting beta 2-agonist  
Exacerbations affect activity;  
Exacerbations 2 times a week or more; may last days  
Nighttime symptoms  $> 1$  time a week  
FEV1 or PEF  $> 60\% - < 80\%$  predicted  
PEF variability  $> 30\%$

4. Has evidence of specific allergic sensitivity; i.e., a positive skin test or in vitro reactivity to a perennial aeroallergen.
5. Has an IgE level of  $> \text{ or } =$  to 30 IU/ml and  $< \text{ or } =$  to 700 IU/ml.
6. Is **inadequately** controlled for 6 months despite use of standard therapies; i.e.:
  - a) a combination of medium dose inhaled corticosteroid and a long-acting beta 2 agonist inhaler; or
  - b) a combination of medium dose inhaled corticosteroid and a leukotriene inhibitor.
7. Is also being treated with one of the following rescue medications due to inadequate control:
  - a) Frequent (2 or more episodes/week) use of a short-acting beta2 agonist; or
  - b) Use of high dose inhaled corticosteroids to maintain adequate control; or
  - c) Frequent (4 or more per year) short courses of systemic corticosteroids (not oral steroid dependent) to maintain adequate control.
8. Has been compliant with medication usage, peak flow monitoring, regular physician follow-up, and avoidance of triggering allergens as much as possible.

#### PRIOR AUTHORIZATION

1. Medicaid Managed Care (Share Advantage, Primary Care Plus): contact the Plan for prior authorization requirements and procedures.
2. Medicaid fee for service:
  - a) The prior authorization request must be done in writing by the asthma specialist – either by using the NE Medicaid prior authorization form or by physician letter addressing how the patient meets the Medicaid coverage criteria as listed above.
    1. A prior authorization form is attached to this provider bulletin for providers wishing to use it.
    2. The form is also available on the HHS website:  
[www.hhs.state.ne.us/med/medindex.htm](http://www.hhs.state.ne.us/med/medindex.htm).
  - b) Medical records must be submitted with the written request documenting how the patient's medical condition meets the Medicaid coverage criteria. This information is to be forwarded to the Program Specialist - Physicians Services at P.O. Box 95026, Lincoln, NE 68509, or by fax at (402) 471-9092.

c) *Medicaid approval will initially be issued for a 3–6 month trial period. Any additional coverage for IgE blocker therapy must be prior authorized by the end of the six-month period and yearly thereafter.*

1. Subsequent prior authorization requests are to be in writing, as was the initial request.
2. Interim medical records are to be submitted with each subsequent prior authorization request.

Coverage of the drug for **home** use is available only in extenuating circumstances and must be prior authorized separately through the **Medicaid Pharmacy Program**; rationale for home use must be included with the request. Coverage of home health services for the administration of the drug must also be prior authorized by the home health agency following the standard Medicaid home health prior authorization procedure.

#### BILLING INSTRUCTIONS

1. Medicaid Managed Care – contact the Plan for specific billing instructions.
2. Medicaid fee for service
  - A. Xolair® currently does not have a CPT or HCPCS code. To bill for the drug, use the miscellaneous J3490. Indicate the name of the drug, the amount given (in milligrams) and the NDC on the claim form.
  - B. Attach a copy of your invoice to the claim form. This will be required even after the drug receives a CPT or HCPCS code.
  - C. Use the appropriate CPT code for the administration of the drug.
  - D. Use the appropriate level E&M code for the office visit.

If you have any questions or concerns about this information, please call:

Physician Services	Lorelee Novak, R.N.	(402) 471-9368
Pharmacy Services	Dyke Anderson, R.P.	(402) 471-9379
Home Health Services	Wendy Isham, R.N.	(402) 471-9386

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**NE Medicaid IgE Blocker Therapy for Asthma Prior Authorization Form**

Patient's Name \_\_\_\_\_

Medicaid ID: \_\_\_\_\_ Patient's date of birth: \_\_\_\_\_

Ordering Physician (please print) \_\_\_\_\_

Physician's Address \_\_\_\_\_

Physician's Phone \_\_\_\_\_ Physician's Fax Number \_\_\_\_\_

Please indicate: \_\_\_\_\_ Initial request or \_\_\_\_\_ Subsequent request

The patient's submitted medical record documents that **all** of the following criteria are met: The patient...

- \_\_\_\_\_ 1. Is age 12 or older; **and**
- \_\_\_\_\_ 2. Has had moderate persistent or severe persistent asthma for at least 1 year (circle all that apply); **and**  

<u>Severe Persistent:</u> Continual symptoms Limited physical activity Frequent exacerbations  Nighttime symptoms frequent FEV1 or PEF < or = 60% predicted PEF variability > 30%	<u>Moderate Persistent:</u> Daily symptoms (e.g. coughing, wheezing, dyspnea) Daily use of inhaled short acting beta 2-agonist Exacerbations affect activity; Exacerbations 2 times a week or more; may last days Nighttime symptoms > 1 time a week FEV1 or PEF >60% -<80% predicted PEF variability > 30%
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- \_\_\_\_\_ 3. Has evidence of specific allergic sensitivity, i.e, a positive skin test or in vitro reactivity to a perennial aeroallergen;  
TEST RESULT \_\_\_\_\_ Date \_\_\_\_\_; **and**
- \_\_\_\_\_ 4. Has an IgE level of >or = 30 IU/ml and < or = 700; LEVEL \_\_\_\_\_ Date \_\_\_\_\_; **and**
- \_\_\_\_\_ 5. Is inadequately controlled for 6 months despite use of standard therapies (circle one that applies):
  - a. combination of medium dose inhaled corticosteroid and a long-acting beta2 agonist inhaler; or
  - b. combination of medium dose inhaled corticosteroid and a leukotriene inhibitor; **and**
- \_\_\_\_\_ 6. Is also being treated with one of the following rescue medications due to inadequate control (circle one that applies):
  - a. Frequent (2 or more episodes/week) use of a short acting beta2 agonist; or
  - b. Use of high dose inhaled corticosteroids to maintain adequate control; or
  - c. Frequent (4 or more per year) short courses of systemic corticosteroids (not oral steroid dependent) to maintain adequate control; **and**
- \_\_\_\_\_ 7. Has been compliant with medication usage, peak flow monitoring, regular physician follow-up, and avoidance of triggering allergens as much as possible; **and**
- \_\_\_\_\_ 8. Evaluation and medical records of the asthma specialist who is prescribing IgE blocker therapy are attached.

Any additional physician comments: \_\_\_\_\_

Physician's Signature \_\_\_\_\_ Date \_\_\_\_\_

Submit this form and medical records to Nebraska Medicaid Physicians Program Specialist by:

**FAX: (402) 471-9092; or Mail at P.O. Box 95026, Lincoln, NE 68509**

**For HHSS Medicaid Internal Use Only:**

- \_\_\_\_\_ Approval for Initiation of IgE Blocker Therapy for first 6 months from \_\_\_\_\_ to \_\_\_\_\_  
(IgE blocker therapy that does not improve patient's asthma control after 3 months should be re-evaluated; treatment beyond 3 months with no improvement may not be covered by Medicaid)
- \_\_\_\_\_ Approval for Ongoing Therapy for 12 months from \_\_\_\_\_ to \_\_\_\_\_
- \_\_\_\_\_ Denied Rationale \_\_\_\_\_
- \_\_\_\_\_ Unable to determine \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_