FIDELIS CARE

PHARMACY SERVICES CLINICAL CRITERIA

Bevacizumab (Avastin®)

POLICY: Fidelis Care may authorize request for Bevacizumab when appropriate criteria are met

PRODUCT RELEVANCE: Child Health Plus (CHP), Medicaid Managed Care, HealthierLife (HARP), Health Exchange, Essential Plan

BENEFIT ALLOCATION: Medical

Product	HCPCS	PA Requirement
Bevacizumab (Avastin®)	J9035	Yes
Bevacizumab-awwb (Mvasi®)	Q5107	No
Bevacizumab-bvzr (Zirabev®)	Q5118	No

PROCEDURE:

1. **Prior authorization requirement:** Providers who prescribe Bevacizumab (Avastin®) are required to obtain prior authorization for members.

2. **Provider requirements:** Bevacizumab (Avastin®) may be requested by a provider with experience in the disease being treated.

3. **Requesting**: An authorization request form must be completed by the provider (or designated agent) to ensure the appropriate collection of essential information to determine medical necessity.

4. **Coverage determination:** Coverage reviews will be conducted in accordance with timeframes outlined in Pharmacy Services Policy 4.100A.

5. **Coverage Criteria**:
    - A. Inadequate response, intolerance, or contradiction to a trial of Mvasi® and Zirabev® (reason for intolerance required)
        - a) Exceptions:
            - i. Requested indication is for ophthalmic use OR ovarian (epithelial), fallopian tube, or primary peritoneal cancer
            - ii. Member has already started on Avastin® and must complete current treatment
    - B. Request is for a FDA-approved or compendia-supported indication
        - a) Oncology- (meets Global Oncology Criteria to support diagnosis)
    - C. Dosing schedule is consistent with the Food and Drug Administration (FDA) product labeling, official compendia, practice guidelines and/or peer-reviewed literature

6. **Approval Duration:**
    - A. Initial: 6 months
    - B. Renewal: 6 months

REFERENCES:

1. Lexicomp Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; Available at: http://online.lexi.com. Accessed on January 21, 2020.

2. Micromedex® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed on January 21, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Available at: http://www.clinicalpharmacology.com. Accessed January 21, 2020.

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FIDELIS CARE

PHARMACY SERVICES CLINICAL CRITERIA

Trastuzumab (Herceptin, Ontruzant, Herzuma, Kanjinti, Herceptin Hylecta)

POLICY: Fidelis Care may authorize request for Trastuzumab (Herceptin, Ontruzant, Herzuma, Kanjinti, Herceptin Hylecta) when appropriate criteria are met

PRODUCT RELEVANCE: Child Health Plus (CHP), Medicaid Managed Care, HealthierLife (HARP), Health Exchange, Essential Plan

BENEFIT ALLOCATION: Medical

Product	HCPCS	PA Requirement
Trastuzumab (Herceptin)	J9355	Yes
Trastuzumab Hyaluronidase-oysk (Herceptin Hylecta)	J9356	Yes
Trastuzumab-dttb (Ontruzant)	Q5112	Yes
Trastuzumab-pkrb (Herzuma)	Q5113	Yes
Trastuzumab-dkst (Kanjinti)	Q5117	Yes
Trastuzumab-anns (Trazimera)	Q5116	No
Trastuzumab (Ogivri)	Q5114	No

PROCEDURE:

7. **Prior authorization requirement:** Providers who prescribe Trastuzumab (Herceptin, Ontruzant, Herzuma, Kanjinti, Herceptin Hylecta) are required to obtain prior authorization for members.

8. **Provider requirements:** Trastuzumab (Herceptin, Ontruzant, Herzuma, Kanjinti, Herceptin Hylecta) may be requested by a provider with experience in the disease being treated.

9. **Requesting**: An authorization request form must be completed by the provider (or designated agent) to ensure the appropriate collection of essential information to determine medical necessity.

10. **Coverage determination:** Coverage reviews will be conducted in accordance with timeframes outlined in Pharmacy Services Policy 4.100A.

11. **Coverage Criteria**:
    - A. Inadequate response, intolerance, or contraindication to a trial of Trazimera AND Ogivri (reason for intolerance required)
        - a) Exception: Member has already started on Herceptin, Ontruzant, Herzuma, Kanjinti, or Herceptin Hylecta and must complete current treatment
    - B. Request is for a FDA-approved or compendia-supported indication
        - a) Oncology- (meets Global Oncology Criteria to support diagnosis)
    - C. Dosing schedule is consistent with the Food and Drug Administration (FDA) product labeling, official compendia, practice guidelines and/or peer-reviewed literature

12. **Approval Duration:**
    - A. Initial: 6 months
    - B. Renewal: 6 months

REFERENCES:

4. Lexicomp Online, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; Available at: http://online.lexi.com. Accessed on January 21, 2020.
5. Micromedex® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed on January 21, 2020.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Available at: http://www.clinicalpharmacology.com. Accessed January 21, 2020.

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FIDELIS CARE

PHARMACY SERVICES **CLINICAL CRITERIA**

Omalizumab (Xolair®)

PROTOCOL: Fidelis Care may authorize a request for Omalizumab (Xolair®) when appropriate criteria are met

PRODUCT RELEVANCE: Child Health Plus (CHP), Medicaid Managed Care, HealthierLife (HARP)

BENEFIT ALLOCATION: Medical [J2357]

PROCEDURE:

13. **Prior authorization requirement:** Providers who prescribe Omalizumab (Xolair®) are required to obtain prior authorization for members.

14. **Provider requirements:** Omalizumab (Xolair®) may be requested by a physician with experience in the disease being treated.

15. **Requesting:** An authorization request form must be completed by the provider (or designated agent) to ensure the appropriate collection of essential information to determine medical necessity.

16. **Coverage determination:** Coverage reviews will be conducted in accordance with timeframes outlined in Pharmacy Services Policy 4.100A.

17. **Coverage Criteria**:
    A. Moderate to Severe Asthma
        a) Member is 6 years of age or older
        b) Positive skin test or in vitro reactivity to perennial allergen e.g. dust mite, animal dander, or mold
        c) FEV1 (forced expiratory volume in 1 second) <80% predicted (prior to receiving any treatment)
        d) Baseline (pre-treatment) serum IgE level ≥ 30 IU/mL per hard copy lab report or medical records
        e) Inadequate response or intolerance to a **recent** 3 month consecutive trial of concomitant use of the following as seen in claims or medical records:
            i. Medium to High potency Inhaled corticosteroid (ICS) + long acting beta agonist (LABA); e.g. Advair, Dulera, or Symbicort **AND**
            ii. Leukotriene receptor antagonist (LTRA) OR Spiriva Respimat
        f) Dose does not exceed 375 mg administered every 2 weeks
        g) Xolair is not prescribed concurrently with Cinqair, Fasenra, Dupixent, or Nucala

    B. **Chronic Idiopathic Urticaria (CIU) / Chronic Spontaneous Urticaria (CSU)**
        a) Member is 12 years of age or older
        b) Dose does not exceed 300 mg administered every 4 weeks
        c) Inadequate response or intolerance to the following as shown by per claims or medical records:
            i. Dose advancement of one Second Generation Antihistamine (sgAH) by 4 times the FDA-indicated dose for 4 weeks duration (e.g. cetirizine, fexofenadine, loratadine)
                i. **IF INTOLERANT** (adverse reaction must be noted) to one sgAH FDA-indicated dose of the sgAH by 4-fold), at least 3 of the following bullets must be added to the maximally tolerated dose of the sgAH:
                    - Another sgAH (e.g. levocetirizine, cetirizine, fexofenadine, loratadine)
                    - H_2 antagonist (e,g, famotidine, ranitidine, cimetidine)

- Leukotriene receptor antagonist for at least 6 weeks (e.g. montelukast, zafirlukast)
- 1st generation antihistamine at bedtime (e.g. hydroxyzine, doxepin, diphenhydramine)
- Dose advancement of potent antihistamine (e.g. hydroxyzine 50 mg 3-4 times daily or doxepin 150 mg at bedtime)

18. **Renewal Criteria**
    a. Member is stable or responding to therapy
    b. Dosing schedule is consistent with product labeling

19. **Approval Duration:**
    A. Initial: 6 months
    B. Renewal: 6 months

REFERENCES:

1. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; 2018, September.
2. American Academy of Allergy, Asthma, & Immunology. Diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol.* 2014;133:1270-1277.
3. Khan DA. Chronic urticaria: Treatment of refractory symptoms In: UptoDate, Saini S, Callen J, (Ed.), Waltham (MA): UpToDate; 2016.
4. Lexi-Comp ONLINE. Hudson (OH): Lexi-Comp, Inc.; Available at: http://online.lexi.com. Accessed on February 21, 2020.
5. Micromedex Solutions ONLINE. Truven Health Analytics. Available at: www.micromedexsolutions.com. Accessed on February 21, 2020.
6. Kolkhir P, Pogorelov D, Darlenski R, Caminati M, Tanno LK, et al. Management of chronic spontaneous urticaria: a worldwide perspective. *World Allergy Organization Journal.* July 2018: 11:14. Online available: https://doi.org/10.1186/s40413-018-0193-4; Accessed on January 15, 2019.
7. Zuberir T, Aberer W, Asero R, Abdul Latiff AH, Baker D, Ballmer-Weber B, Bernstein JA et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticarial. *Allergy*. 2018;73:1393–1414. Online available: https://onlinelibrary.wiley.com/doi/full/10.1111/all.13397; Accessed February 21, 2020.
8. Global Initiative for Asthma: Global strategy for asthma management and prevention (2018 update). Available at: https://ginasthma.org/2018-gina-report-global-strategy-for-asthma- management-and-prevention/. Accessed November 13, 2018.
9. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UptoDate, Bochner BS, Hollingsworth H, (Ed.), Waltham (MA): UpToDate; 2019.

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