A Public Entity

Inland Empire Health Plan

IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Biosimilar Products	**Guideline #**	UM_OTH 22
		Original Effective Date	5/13/20
Section	Other	**Revised Date**	

COVERAGE POLICY

A. Biosimilar drugs are preferred when there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:

1. Treatment with at least two (2) associated biosimilar drug(s) has been ineffective, not tolerated, or is contraindicated;
2. Prescribing physician attests that failure, intolerance, or contraindication would not be expected to occur with Reference drug;
3. Requested dosage is consistent with FDA approved labeling
4. Prescribed for an FDA approved indication
5. Prescribed for a non-FDA approved indication recognized by DRUGDEX Information System as recommended regimen of category 2B or above

B. Continued therapy
   1. Duration of therapy: 6 months
   2. Reauthorization requires the following:
      a. Documentation supporting patient stability and positive clinical response (i.e. chart notes, relevant lab values, etc.)
      b. Dosages and duration of therapy must not exceed standard of care, package insert information, or established clinical practice guidelines
      c. Duration of Reauthorization: 180 days

C. Preferred biosimilar drugs and corresponding reference drug
   1. **ANTI-INFLAMMATORY**
      a. Preferred Biosimilar Drugs: **Eticovo** (etanercept-ykro), **Erelzi** (etanercept-sz)
         i. Reference Drug**: Enbrel** (etanercept)
      b. Preferred Biosimilar Drugs: **Abrilada** (adalimumab-afzb), **Amjevita** (adalimumab -atto), **Cyltezo** (adalimumab-adbm), **Hadlima** (adalimumab-bwwd), **Hyrimoz** (adalimumab-adaz)
         i. Reference Drug: **Humira** (adalimumab)
      c. Preferred Biosimiliar Drug: **Avsola** (infliximab-axxq), Inflectra (infliximab-dyyb), Ixifi (infliximab-qbtx), Renflexis (infliximab-abda)
         i. Reference Drug: **Remicade** (infliximab)

2. **ANTINEOPLASTIC/ANTI-INFLAMMATORY**
    a. Preferred Biosimilar Drugs: **Mvasi** (bevacizumab-awwb), **Zirabev** (bevacizumab-bvzr)
        i. Reference Drug: Avastin (bevacizumab)
    b. Preferred Biosimilar Drugs: **Herzuma** (trastuzumab-pkrb), **Kanjinti** (trastuzumab-anns), **Ogivri** (trastuzumab-dkst), **Ontruzant** (trastuzumab-dttb), **Trazimera** (trastuzumab-qyyp)
        i. Reference Drug: **Herceptin** (trastuzumab)
    c. Preferred Biosimilar Drugs: **Ruxience** (rituximab-pvvr), **Truxima** (rituximab-abbs)
        i. Reference Drug: **Rituxan** (rituximab)

3. **HEMATOLOGY**
    a. Preferred Biosimilar Drugs: **Retacrit** (epoetin alfa-epbx)
        i. Reference Drugs: **Epogen, Procrit** (epoetin alfa)
    b. Preferred Biosimilar Drugs: Nivestim (filgrastim-aafi), Zarxio (filgranstim-sndz)
        i. Reference Drug: **Neupogen** (filgrastim)
    c. Preferred Biosimilar Drugs: **Fulphila** (pegfilgrastim-jmdb), **Udenyca** (pegfilgrastim-cbqv)**, Ziextenzo** (pegfilgrastim-bmez)
        i. Reference Drug: **Neulasta** (pegfilgrastim)

COVERAGE LIMITATION AND EXCLUSIONS

A. Biosimilar coverage does not include the following:
    1. Requests for off-labeled use or investigational use
    2. Requests that are not considered medically necessary or appropriate
    3. Requests for patients with history of contraindication and medical intolerance to the requested drugs

ADDITIONAL INFORMATION

Applicable Codes

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement policy.

Drug Name	HCPCS Code	Description
Enbrel (etanercept)	J1438	Injection, etanercept, 25 mg
Erelzi (etanercept-szzs)	C9399, J3590	Unclassified drugs or biologicals
Eticovo (etanercept-ykro)	C9399, J3590	Unclassified drugs or biologicals
Humira (adalimumab)	J0135	Injection, adalimumab, 20 mg
Abrilada (adalimumab-afzb)	C9399, J3590	Unclassified drugs or biologicals
Amjevita (adalimumab-atto)	C9399, J3590	Unclassified drugs or biologicals
Cyltezo (adalimumab-adbm)	C9399, J3590	Unclassified drugs or biologicals
Hadlima (adalimumab-bwwd)	C9399, J3590	Unclassified drugs or biologicals
Hyrimoz (adalimumab-adaz)	C9399, J3590	Unclassified drugs or biologicals
Remicade (infliximab)	J1745	Injection, infliximab, excludes biosimilar, 10 mg
Avsola (infliximab-axxq)	C9399, J3590	Unclassified drugs or biologicals
Inflectra (infliximab-dyyb)	Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Ixifi (infliximab-qbtx)	Q5109	Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg
Renflexis (infliximab-abda)	Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Avastin (bevacizumab)	J9035	Injection, bevacizumab, 10 mg
Mvasi (bevacizumab-awwb)	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Zirabev (bevacizumab-bvzr)	Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
Herceptin (trastuzumab)	J9355	Injection, trastuzumab, 10 mg
Herzuma (trastuzumab-pkrb)	Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Kanjinti (trastuzumab-anns)	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg

Ogivri (trastuzumab-dkst)	Q5114	Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Ontruzant (trastuzumab-dttb)	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10mg
Trazimera (trastuzumab-qyyp)	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Rituxan (rituximab)	J9312	Injection, rituximab, 10 mg
Ruxience (rituximab-pvvr)	J9999	Not otherwise classified, antineoplastic drug
Truxima (rituximab-abbs)	Q5115	Injection, rituximab-abbs, biosimilar, 10 mg
Epogen, Procrit (epoetin alfa)	J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units
	Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
Retacrit (epoetin alfa-epbx)	Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units
	Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-ESRD use), 1000 units
Neupogen (filgrastim)	J1442	injection, **filgrastim** 1 mcg
Nivestim (filgrastim-aafi)	Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
Zarxio (filgrastim-sndz)	Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram1
Neulasta (pegfilgrastim)	J2505	Injection, pegfilgrastim, 6mg
Fulphila (pegfilgrastim-jmdb)	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5mg
Udenyca (pegfilgrastim-cbqv)	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5m
Ziextenzo (pegfilgrastim-bmez)	C9058	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg

CLINICAL/REGULATORY RESOURCE

1. The Centers for Medicare and Medicaid Services (CMS) primarily address payment for use of biosimilar drugs using codes that distinguish manufacturers of specific biosimilar drugs from the reference drugs and from one another.
2. Biosimilar drugs listed in the Medi-Cal Provider Manual may be approved for FDA approved indications, dosages and usages. Policy related to billing for injection services lists individual drugs by generic drug name.
3. Neither MCG Health nor Apollo Managed Care have guidelines on biosimilar drugs.

4. The U.S. Food and Drug Administration (FDA) states that a proposed biosimilar demonstrate close similarity to the reference product through extensive analysis of purity, chemical identity and bioactivity of both the reference product and the proposed biosimilar.

   The proposed biosimilar product must also show no clinically meaningful differences from the reference product in terms of safety, and potency. This is generally demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.

DEFINITION OF TERMS

1. Biosimilar – A biological product that is highly similar to the FDA-approved originator (reference) product with the exception of minor differences in clinically inactive components and no differences in efficacy, safety and purity.
2. Reference Drug – A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared.

REFERENCES

1. Centers for Medicare & Medicaid Services. Part B Biosimilar Biological Product Payment and Required Modifiers. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment. Accessed April 21, 2020.
2. California Department of Health Care Services, 2019. Medi-Cal Provider Manual, Chemotherapy:An Overview.
3. U.S. Food and Drug Administration. Biosimilar and Interchangeable Products. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed April 15, 2020.
4. U.S. Food and Drug Administration. Biological Product Definitions. Available at: https://www.fda.gov/drugs/biosimilars/health-care-provider-materials#fact. Accessed April 21, 2020.
5. U.S. Food and Drug Administration. Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations. Available at: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or. Accessed April 21, 2020.

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