2024 – Martin's Point Health Care Generations Advantage
Part B Drug & Biologic Injectables Step Therapy Clinical Guideline

This clinical guideline informs prescribers of preferred products and provides an exception process for the non-preferred products through prior authorization.

- This program applies to the Part B medical benefit injectable products specified in this policy. (Step therapy requirements do not apply to requests for services supplied by non-par LPPO providers.)
- Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product.
- The coverage review process will ascertain situations where a clinical exception can be made.
- This program applies to members who are initiating treatment with a non-preferred product. (A member is considered to be initiating treatment when using the non-preferred product for the first time or the non-preferred product has not been used within the last 365 days.)

Part B Step Therapy requirements are intended to be used in addition to applicable Medicare NCDs, LCDs, and manuals. In the case of a discrepancy between this clinical guideline and Medicare coverage determinations, manuals or the member's Evidence of Coverage Documents (EOC), the Medicare NCD, LCD, manuals or EOC will rule.

Prior Authorization will be required for ALL step therapy products included in this clinical guideline unless specifically indicated otherwise in the Step Therapy Preferred Products List.

The following preferred product types are included in this clinical guideline:

Step Therapy Preferred Products List	
Product Type	**Preferred Product**
Acromegaly Products	Lanreotide Injection, Sandostatin LAR
Alpha-1 Proteinase Inhibitors	Prolastin-C
Asthma (Severe) Products	Fasenra, Xolair
Autoimmune – Infliximab Antirheumatic Products	Avsola, Inflectra
Autoimmune – Other Antirheumatic Products	Entyvio, Simponi Aria
Bevacizumab Products (Non-Ocular)	Mvasi
Botulinum Toxins	Dysport, Xeomin
Colony Stimulating Factors (Long Acting)	Fulphila, Ziextenzo
Colony Stimulating Factors (Short Acting)	Zarxio
Erythropoiesis Stimulating Agents	Aranesp, Retacrit
Gaucher Disease Products	Cerezyme, Elelyso
Gonadotropin Releasing Hormone Agonists for Prostate Cancer	Eligard
*Hyaluronates for Knee Osteoarthritis *(no auth required for the preferred products)*	Single: Orthovisc, Synvisc Multi: Durolane, Synvisc One
Multiple Sclerosis Products	Ocrevus, Tysabri
*Ocular Disorder Products *(no auth required for Avastin for eye indications ONLY)*	Primary: Avastin (no auth) Secondary: Byooviz (auth)
Rituximab	Ruxience, Truxima
Trastuzumab	Kanjinti, Ogivri, Trazimera

ACROMEGALY PREFERRED PRODUCTS: LANREOTIDE INJECTION AND SANDOSTATIN LAR

Preferred	• **J1932 - Lanreotide Injection** (lanreotide acetate) • **J2353 - Sandostatin LAR** (octreotide acetate for injectable suspension)
Non-Preferred	• **J2502 - Signifor LAR** (pasireotide) • **J1930 - Somatuline Depot** (lanreotide)

Acromegaly Product EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a non-preferred product is provided when any of the following criteria is met:

A. Member has received treatment with the requested non-preferred product in the past 365 days.

B. The request is for Signifor LAR and member has a documented inadequate response or intolerable adverse event to any of the preferred products.

C. The request is for Somatuline Depot and both of the following criteria are met:

1. The member has a documented intolerable adverse event to lanreotide injection, and the adverse event was not an unexpected adverse event attributed to the active ingredient as described in the prescribing information.
2. The member has a documented inadequate response or intolerable adverse event to Sandostatin LAR Depot.

ALPHA-1 PROTEINASE INHIBITOR PREFERRED PRODUCT: PROLASTIN-C

Preferred	• **J0256 - Prolastin-C** (alpha$_1$-proteinase inhibitor [human])
Non-Preferred	• **J0256 - Aralast NP** (alpha$_1$-proteinase inhibitor [human]) • **J0257 - Glassia** (alpha$_1$-proteinase inhibitor [human]) • **J0256 - Zemaira** (alpha$_1$-proteinase inhibitor [human])

Alpha-1 Proteinase Inhibitor EXCEPTION CRITERIA

Coverage for a non-preferred product is provided when either of the following criteria are met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

ASTHMA (SEVERE) PREFERRED PRODUCTS: FASENRA AND XOLAIR

Preferred	• **J0517- Fasenra** (benralizumab) • **J2357 - Xolair** (omalizumab)
Non-Preferred	• **J2786 - Cinqair** (reslizumab) • **J2182 - Nucala** (mepolizumab) • **J2356 - Tezspire** (tezepelumab-ekko)

Severe Asthma Product EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for the non-preferred product is provided when either of the following criteria is met:

A. Cinqair

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has both of the following:
   a. Member has a documented inadequate response or intolerable adverse event with Fasenra.
   b. Member has either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

B. Nucala

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets any of the following:
   a. Member has a comorbidity of nasal polyps and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IUmL.
   b. Member is less than 12 years of age and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   c. Member is 12 years of age or older and meets both of the following:
      i. Member has a documented inadequate response or an intolerable adverse event with Fasenra.
      ii. Member has either of the following:
         1. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
         2. A pretreatment serum IgE level of less than 30 IU/mL.

C. Tezspire

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets both of the following:
   a. The member has either of the following:
      i. Blood eosinophil count of at least 150 cells per microliter and has had a documented inadequate response or an intolerable adverse event with Fasenra.
      ii. Blood eosinophil count of less than 150 cells per microliter.
   b. The member has either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

AUTOIMMUNE DISEASE-MODIFYING ANTIRHEUMATIC OTHER PREFERRED PRODUCTS: ENTYVIO AND SIMPONI ARIA IV

Preferred*	• **J3380 - Entyvio** (vedolizumab) • **J1602 - Simponi Aria IV** (golimumab)
Non-Preferred	• **J3262 - Actemra** (tocilizumab) • **J0717 - Cimzia** (certolizumab pegol) • **J3245 - Ilumya** (tildrakizumab-asmn) • **J0129 - Orencia** (abatacept) • **J3358 - Stelara IV** (ustekinumab) • **J3357 - Stelara SQ** (pharmacy-Part D)

Autoimmune Other Antirheumatic Product EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a non-preferred product is provided when any of the following criteria is met:

A. For Cimzia, when any of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both Entyvio and Simponi Aria where the product's indications overlap.
3. Member is currently breastfeeding, pregnant, or planning pregnancy.

B. For all other non-preferred products, when any of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both Entyvio and Simponi Aria where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

III. APPENDIX: Clinical reasons to avoid TNF inhibitors

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- History or risk of lymphoma or other malignancy
- History of being a primary non-responder to a TNF inhibitor

AUTOIMMUNE DISEASE-MODIFYING ANTIRHEUMATIC INFLIXIMAB PREFERRED PRODUCTS: AVSOLA AND INFLECTRA

Preferred	• **Q5103 - Inflectra** (infliximab-dyyb) • **Q5121 - Avsola** (infliximab-axxq)
Non-Preferred	• **J1745** - **Infliximab** • **J1745 - Remicade** (infliximab) • **Q5104 - Renflexis** (infliximab-abda)

Autoimmune Infliximab Antirheumatic Product EXCEPTION CRITERIA

Coverage for a non-preferred product is provided when any of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

BEVACIZUMAB NON-OCULAR INDICATIONS PREFERRED PRODUCT: MVASI

Preferred	• **Q5107 - Mvasi** (bevacizumab-awwb)
Non-Preferred	• **J9035 or C9257 - Avastin** (bevacizumab) • **Q5126 – Alymsys (**bevacizumab-maly) • **Q5129 – Vegzelma** (bevacizumab – adcd) • **Q5118 - Zirabev** (bevacizumab-bvzr)

Bevacizumab for Non-Ocular Indications EXCEPTION CRITERIA

Coverage for the non-preferred product is provided when any of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has had a documented intolerable adverse event to the preferred product, Mvasi, and the adverse

C. event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

BOTULINUM TOXINS PREFERRED PRODUCTS: DYSPORT AND XEOMIN

Preferred	• **J0586 - Dysport** (abobotulinumtoxinA) • **J0588 - Xeomin** (incobotulinumtoxinA)
Non-Preferred	• **J0585 - Botox** (onabotulinumtoxinA) • **J0587 - Myobloc** (rimabotulinumtoxinB)

Botulinum Toxin EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.
Coverage for a non-preferred product is provided when ANY of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has a documented inadequate response or intolerable adverse event to both of the preferred products.

C. Member is requesting Botox for the treatment of blepharospasm and either of the following criteria is met:
   1. Member is 18 years of age and older and the member has had a documented inadequate response or intolerable adverse event to Xeomin
   2. Member is 12 years of age or older but less than 18 years of age

D. Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport.

E. Member is requesting Botox for the treatment of upper limb spasticity and both of the following criteria are met:
   1. Member is a pediatric patient 2 years of age to 17 years of age and the upper limb spasticity is caused by cerebral palsy.
   2. Member has had a documented inadequate response or adverse event to Dysport.

F. Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event to Xeomin.

COLONY STIMULATING FACTOR (LONG ACTING) PREFERRED PRODUCTS: FULPHILA and ZIEXTENZO

Preferred	• **Q5108 - Fulphila** (pegfilgrastim-jmdb) • **Q5120 - Ziextenzo** (pegfilgrastim-bmez)
Non-Preferred	• **Q5130 - Fylnetra** (pegfilgrastim-pbbk) • **J2506 - Neulasta (including Onpro kit)** (pegfilgrastim) • **Q5122 - Nyvepria (**pegfilgrastim-apgf) • **J1449 - Rolvedon** (eflapegrastim-xnst) • **Q5127 - Stimufend** (pegfilgrastim-fpgk) • **Q5111 - Udenyca** (pegfilgrastim-cbqv)

Colony Stimulating Factors (Long Acting) EXCEPTION CRITERIA

Coverage for the non-preferred products is provided when either of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days

B. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference products and biosimilar products).

COLONY STIMULATING FACTORS (SHORT ACTING) PREFERRED PRODUCT: ZARXIO

Preferred	• **Q5101 - Zarxio** (filgrastim-sndz)
Non-Preferred	• **J1447 - Granix** (TBO-filgrastim) • **J2820 - Leukine** (sargramostim) • **J1442 - Neupogen** (filgrastim) • **Q5110 - Nivestym** (filgrastim-aafi) • **Q5125 – Releuko** (filgrastim-ayow)

Colony Stimulating Factors (Short Acting) EXCEPTION CRITERIA

A. Neupogen, Granix, Nivestym, or Reluko

Coverage for the non-preferred products, Neupogen or Granix, is provided when the member meets one of the following criteria:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
3. Member has a documented latex allergy and the prescriber states that the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
4. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

B. Leukine

Coverage for the non-preferred product, Leukine, is provided when the member meets one of the following criteria:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Leukine is being requested for an indication that is not FDA-approved for the preferred product.
3. Member has had a documented inadequate response or an intolerable adverse effect to any of the preferred products.

ERYTHROPOIESIS STIMULATING AGENTS PREFERRED PRODUCT: ARANESP AND RETACRIT

Preferred	• **J0881 - Aranesp** (darbepoetin alfa) • **Q5106 - Retacrit** (epoetin alfa)
Non-Preferred	• **J0885 - Epogen** (epoetin alfa) • **J0888 - Mircera** (methoxy polyethylene glycol-epoetin beta) • **J0885 - Procrit** (epoetin alfa)

Erythropoiesis Stimulating Agents EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

A. Mircera

Coverage for non-preferred product, Mircera, is provided when either of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Retacrit.

B. Epogen or Procrit

Coverage for either of the non-preferred products, Epogen or Procrit, is provided when either of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets both of the following criteria:
    a. Member has a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.
    b. Member has a documented intolerable adverse event with the preferred product, Retacrit, which was NOT an expected adverse event attributed to the active ingredient as described in the prescribing information.

GAUCHER DISEASE AGENTS PREFERRED PRODUCTS: CEREZYME AND ELELYSO

Preferred	• **J1786 - Cerezyme** (imiglucerase) • **J3060 - Elelyso** (taliglucerase alfa)
Non-Preferred	• **J3385 - VPRIV** (velaglucerase alfa)

Gaucher Disease Agents EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a non-preferred product is provided when either of the following criteria are met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerezyme and Elelyso.

GONADOTROPIN RELEASING HORMONE AGONISTS PREFERRED PRODUCT: ELIGARD

Preferred	• **J9217 - Eligard** (leuprolide acetate for depot suspension)
Non-Preferred	• **J1952 – Camcevi** (leuprolide mesylate) • **J9217 - Lupron Depot** (leuprolide acetate for depot suspension) • **J3315 - Trelstar** (triptorelin) • **J9202 - Zoladex** (goserelin acetate)

Gonadotropin Releasing Hormone Agonists EXCEPTION CRITERIA

This applies to members requesting treatment for prostate cancer.

Coverage for a non-preferred product is provided when either of the following criteria is met:

A. Member has received treatment with a non-preferred product in the past 365 days.

B. Member has a documented hypersensitivity to the preferred product.

HYALURONATES PREFERRED PRODUCTS: DUROLANE, ORTHOVISC, SYNVISC AND SYNVISC ONE

Preferred Products (Osteoarthritis – MULTI): Orthovisc and Synvisc
Preferred Products (Osteoarthritis – SINGLE): Durolane and Synvisc-One

Table 1. Hyaluronate products (Osteoarthritis - MULTI)

Preferred (No Auth)	• **J7324 - Orthovisc** (high molecular weight hyaluronan) • **J7325 - Synvisc** (hylan G-F 20)
Non-Preferred	• **J7323 - Euflexxa** (1% sodium hyaluronate) • **J7328 - Gelsyn-3** (sodium hyaluronate) • **J7320 - GenVisc 850** (sodium hyaluronate) • **J7321 - Hyalgan** (sodium hyaluronate) • **J7322 - Hymovis** (high molecular weight viscoelastic hyaluronan) • **J7321 - Supartz FX** (sodium hyaluronate) • **J7332 - Triluron** (sodium hyaluronate) • **J7329 - Trivisc** (sodium hyaluronate) • **J7321 - Visco-3** (sodium hyaluronate)

Table 2. Hyaluronate products (Osteoarthritis - SINGLE)

Preferred (No Auth)	• **J7318 - Durolane** (hyaluronic acid) • **J7325 - Synvisc One** (hylan G-F 20)
Non-Preferred	• **J7326 - Gel-One** (cross-linked hyaluronate) • **J7327 - Monovisc** (high molecular weight hyaluronan)

Hyaluronates EXCEPTION CRITERIA *(Does not apply to LCD off-label shoulder indications)*

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a non-preferred product is provided when either of the following criteria is met:

A. Osteoarthritis – MULTI Injections

Coverage for a non-preferred product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.
B. Member has a documented intolerable adverse event to both of the preferred products, Orthovisc and Synvisc.

B. Osteoarthritis -SINGLE Injection

Coverage for a non-preferred product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.
B. Member has a documented intolerable adverse event to both of the preferred products, Durolane and Synvisc-One.

MULTIPLE SCLEROSIS PREFERRED PRODUCTS: OCREVUS AND TYSABRI

Preferred	• **J2350 - Ocrevus** (ocrelizumab) • **J2323 - Tysabri** (natalizumab)
Non-Preferred	• **J2329 - Briumvi** (ublituximab-xiiy) • **J0202 - Lemtrada** (alemtuzumab)

Multiple Sclerosis (MS) Product EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the non-preferred product is provided when any of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has a documented inadequate response, intolerance or contraindication to therapy with both of the preferred products or any of their components.

OCULAR DISORDERS PREFERRED PRODUCTS: AVASTIN (Primary) & BYOOVIZ (Secondary)

Primary Preferred (No Auth)	• **J9035 or C9257 - Avastin** (bevacizumab)
Secondary Preferred	• **Q5124 – Byooviz** (ranibizumab-nuna)
Non-Preferred	• **J0179 - Beovu** (brolucizumab-dbll) • **Q5128 - Cimerli** (ranibizumab-eqrn) • **J0178 - Eylea** (aflibercept) • **J2778 - Lucentis** (ranibizumab) • **J2779 - Susvimo** (ranibizumab injection) • **J2777 - Vabysmo** (faricimab-svoa)

Ocular Disorder Product EXCEPTION CRITERIA *(does not apply when LCD coverage diagnoses do not overlap for preferred and non-preferred)*

Coverage for the non-preferred products is provided when either of the following criteria is met:

A. Member has received treatment with the requested non-preferred product in the past 365 days.

B. Member meets any of the following criteria:

1. The requested product is Byooviz and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.

2. The requested product is Beovu or Vabysmo and member has had a documented inadequate response or intolerable adverse event with both of the preferred products (Avastin, Byooviz).

3. The requested product is Eylea and member meets either of the following criteria:
   a. Member has a diagnosis of retinopathy of prematurity.
   b. Member has a documented inadequate response or intolerable adverse event with both of the preferred products (Avastin, Byooviz).

4. The requested product is Cimerli, Lucentis, or Susvimo and member meets both of the following criteria:
   a. Member has had a documented inadequate response or intolerable adverse event with Avastin.
   b. Member has had a documented intolerable adverse event to the preferred product, Byooviz, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

RITUXIMAB PRODUCTS PREFERRED PRODUCTS: RIABNI AND TRUXIMA

Preferred	• **Q5119 - Ruxience** (rituximab-pvvr) • **Q5115 - Truxima** (rituximab-abbs)
Non-Preferred	• **Q5123 - Riabni** (rituximab-arrx) • **J9312 - Rituxan** (rituximab) • **J9311 - Rituxan Hycela** (rituximab and hyaluronidase human)

Rituximab Products EXCEPTION CRITERIA

Coverage for the non-preferred product is provided when either of the following criteria is met:

A. Member has received treatment with the non-preferred product in the past 365 days.

B. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

TRASTUZUMAB PREFERRED PRODUCTS: KANJINTI, OGIVRI, AND TRAZIMERA

Preferred	• **Q5117 - Kanjinti** (trastuzumab-anns) • **Q5114 - Ogivri** (trastuzumab-dkst) • **Q5116 - Trazimera** (trastuzumab-qyyp)
Non-Preferred	• **J9355 - Herceptin** (trastuzumab) • **J9356 - Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Q5113 - Herzuma** (trastuzumab-pkrb) • **Q5112 - Ontruzant** (trastuzumab-dttb)

Trastuzumab Products EXCEPTION CRITERA

Coverage for the non-preferred product is provided when either of the following criteria is met:

A. Member has received treatment with the requested non-preferred product in the past 365 days

B. Member has had a documented intolerable adverse event to all of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

National and Local Coverage Determinations (Billing and Coding Articles):

LCD33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses: LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52370 Billing and Coding **Article: Bevacizumab and Biosimilars** - Article - Billing and Coding: Bevacizumab and biosimilars (A52370) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52420 Billing and Coding **Article: Hyaluronans** Intra-articular Injection of - Article - Billing and Coding: Hyaluronans Intra-articular Injections of (A52420) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52423 Billing and Coding **Article:** Infliximab and Biosimilars: Article - Billing and Coding: Infliximab and biosimilars (A52423) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52453 Billing and Coding **Article: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs** - Article - Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52448 Billing and Coding **Article: Omalizumab** Article - Billing and Coding: Omalizumab (A52448) (cms.gov)

LCD 33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses; A52451 Billing and Coding **Article: Ranibizumab, Aflibercept and Brolucizumab-dbll** - Article - Billing and Coding: Ranibizumab and biosimilars, Aflibercept, Brolucizumab-dbll and Faricimab-svoa (A52451) (cms.gov)

LCD 33646 Botulinum Toxins - LCD - Botulinum Toxins (L33646) (cms.gov); A52848 Billing and Coding **Article: Botulinum Toxins** - Article - Billing and Coding: Botulinum Toxins (A52848) (cms.gov)

LCD 39297 Off-Label Use of Rituximab and Rituximab Biosimilars - LCD - Off-label Use of Rituximab and Rituximab Biosimilars (L39297) (cms.gov); A59101 Billing and Coding **Article: Off-Label Use of Rituximab and Rituximab Biosimilars** - Article - Billing and Coding: Off-label Use of Rituximab and Rituximab Biosimilars (A59101) (cms.gov)

NCD 110.21 **Erythropoiesis Stimulating Agents (ESAS)** in Cancer and Related Neoplastic Conditions - NCD - Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21) (cms.gov)

A59218 Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen - Article - Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen (A59218) (cms.gov)

Product Package Inserts

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; September 2021.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 2021.
5. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2022.
6. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; March 2022.
7. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
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APPROVAL

Approved By	Utilization Management Committee
Approved Date	12/5/2023