PROVIDER REIMBURSEMENT GUIDANCE			
Drugs and Biologicals with Discards			
Original Date Approved	**Effective Date SCO/ICO**	**Effective Date MAPD***	**Revision Date**
09/15/2020	03/01/2022	03/01/2022	02/01/2022

Scope: Commonwealth Care Alliance (CCA) Product Lines

☒ Senior Care Options (MA)
☒ One Care (MA)
☒ CCA Medicare Preferred – (PPO) MA*
☒ CCA Medicare Value - (PPO) MA*
☒ CCA Medicare Preferred – (PPO) RI*
☒ CCA Medicare Value - (PPO) RI*
☒ Medicare Maximum – (HMO DNSP) RI*

PAYMENT POLICY SUMMARY:

Commonwealth Care Alliance (CCA) covers medically necessary drugs and biologicals, and the associated administration services, in accordance with medical necessity guideline (MNG) policies and member benefits.

REIMBURSEMENT REQUIREMENTS:

Drugs covered under the medical benefit (vs. pharmacy benefit) are drugs that require skilled administration by providers (e.g., infused or injected). Medical benefit drugs should be procured by the provider and billed to CCA with the applicable administration code(s).

Providers are responsible for the submission of accurate claims. To be reimbursed, the required drug HCPCS (Healthcare Common Procedure Coding System) or CPT (Current Procedural Terminology) code(s), the number of HCPCS and/or CPT units, the NDC number, unit(s) of measure, and quantity must be submitted. Claims are priced based on HCPCS or CPT codes and associated units of service. If the NDC does not have a specific HCPCS or CPT code assigned, please assign the appropriate miscellaneous drug code.

Drugs and Biologicals

CCA provides limited benefits for outpatient drugs. CCA Medicare Advantage covers drugs that are furnished "incident to" a physician's service provided that the drugs are not self-administered by the patients who take them. Usually, drugs and biologicals are covered only if all the following requirements are met:

- They meet the definition of drugs or biologicals.
- They are of the type that are not generally self-administered.
- They meet all the general requirements for coverage of items as incident to a physician's services.
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice.
- They are not omitted as noncovered immunizations.
- They have not been decided by the FDA (Food and Drug Administration) to be less than effective.
- CCA Medicare Advantage does not generally cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the policy provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs.

Discarded Drugs and Biologicals

Physicians, hospitals, and other providers are expected to care for patients in such a way that they can use/administer drugs or biological products in the most effective and clinically appropriate manner. Providers should administer medications in the most cost-effective manner, utilizing the most cost-effective vial, and/or combination of vial sizes to minimize drug waste.

If a physician, hospital, or other provider must discard the remainder of a single-use vial or package after administering one dose/quantity or the last dose (of the day) of the drug or biological, CCA will compensate for the drug or biological discarded, and the dose administered, up to the next incremental J-code. Medical record documentation must clearly indicate the amount of drug administered and the amount wasted.

CCA will not compensate for pharmaceutical waste and/or unused portions of pharmaceutical vials withdrawn from a multi-dose vial.

JW Modifier

CMS guidelines state to report the drug amount administered on one line, and on a separate line you may report the amount of drug NOT administered (wasted) with modifier –JW appended to the associated HCPCS code.

Modifier –JW is only applicable to the amount of the drug discarded or wasted, and not the amount administered. Further, the amount wasted and identified using modifier –JW, must be at least equal to one billing unit.

Modifier –JW is not permitted to identify discarded amounts from a multi-dose vial (MDV). To make sure you do not receive overpayment, remember to always roll the amount administered up to the next bill unit, then roll down to the previous bill unit when reporting the amount of drug discarded.

REFERRAL/NOTIFICATION/PRIOR AUTHORIZATION REQUIREMENTS:

For more information on prior authorization, please refer to the Prior Authorization Requirements in the plan specific Provider Manual.

Please see the Pharmacy Program section of the Commonwealth Care Alliance © website for more information on drug coverage.

BILLING AND CODING GUIDELINES:

For Drugs/Biologicals without a corresponding HCPCS code, follow the guidance in the current year HCPCSmanual:

HCPCS for Unlisted Code	Unlisted Code Description
A9699	Radiopharmaceutical, therapeutic, not otherwise classified
J3490	Unclassified Drugs
J3590	Unclassified Biologics
J7599	Immunosuppressive drug, not otherwise classified
J7699	NOC drugs, inhalation solution administered through DME
J7799	NOC drugs, other than inhalation drugs, administered through DME
J7999	Compounded drug, not otherwise classified
J8498	Antiemetic drug, rectal/suppository, not otherwise specified
J8499	Prescription drug, oral, nonchemotherapeutic, NOS
J8597	Antiemetic drug, oral, not otherwise specified
J8999	Prescription drug, oral, chemotherapeutic, NOS
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals

*NOS- Not otherwise specified **NOC- Not otherwise classified

Modifier	Description
JW	Drug amount discarded/not administered to any patient
UD	340B Drugs

NOTE:

All unlisted NOC, NOS, or Unclassified Drugs/Biologicals require the unit of measure, NDC number, and quantity present on the claim.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This information does not take precedence over CCI edits. Please refer to CCI for correct coding guidelines and specific applicable code combinations prior to billing CCA Medicare Advantage.

Any applicable modifiers should be utilized to indicate drug waste on single unit vials.

As of 12/01/2020, CCA will be implementing a new policy for the list of drugs below regarding brand name drugs and Biosimilars affecting the following drugs below. Please reference the Medical Necessity Guidelines for more information.

Drug	Policy Description

Bevacizumab	**Code(s) J9035, Q5107, Q5118**
	• CCA does not usually compensate for bevacizumab when it is billed less than one month following a major surgery.
	• CCA limits coverage to the following when billed by any provider:
	  ○ Once every 6 days
	  ○ Once every 20 days if the diagnosis is non-small cell lung cancer
	  ○ Once every 13 days if the diagnosis is breast cancer, colorectal cancer, glioblastoma, pancreatic cancer, renal cell carcinoma, or soft tissue sarcoma
	  ○ Two units per date of service if the diagnosis is for ophthalmic indications
	• CCA does not usually compensate without an FDA-approved or an off-label recommended indication.
	
	Code: C9257
	• CCA does not compensate unless the diagnosis on the claim is for ophthalmic indications.
	• CCA limits coverage to 20 units.
	• CCA does not compensate when billed by any provider more than twice within a four-week period.
	• CCA will limit 10 combined units per date of service by any provider when the diagnosis is angioid streaks of the choroid, branch retinal vein occlusion with macular edema, central retinal vein occlusion with macular edema, choroidal retinal neovascularization associated with age-related macular degeneration, choroidal retinal neovascularization associated with angioid streaks, cystoid macular degeneration, degenerative myopia, diabetic macular edema, histoplasmosis retinitis, neovascular glaucoma, nondiabetic proliferative retinopathy, proliferative diabetic retinopathy, retinal edema, retinal ischemia, retinal neovascularization, retinal telangiectasia, or rubeosis iridis.

Drug	Policy Description

Epoetin Alfa	**Code(s) J0885, Q5106**
	• CCA may limit coverage to maximum dosages as indicated within the drug package insert or CMS compendia for any of the following:
	  ○ Anemia due to and following chemotherapy.
	  ○ Anemia due to HIV infection, in patients with endogenous serum erythropoietin levels of 500 milliunits/mL or less.
	  ○ Anemia in chronic kidney disease, in patients on dialysis and not on dialysis, to decrease the need for red blood cell transfusion.
	  ○ Surgical procedure, elective, noncardiac, nonvascular - transfusion of blood product, allogeneic, in patients with perioperative hemoglobin greater than 10 to 13 g/dL who are at high risk for blood loss
	• CCA does not usually compensate without an FDA-approved indication or an off-label recommended indication with clinical documentation.

Filgrastim
Pegfilgrastim
	Code(s) J2505, J1442, J1447, Q5018, Q5101, Q5110, Q5111, Q5120, Q5122
	• CCA does not usually compensate if billed by any provider within 11 days prior to the administration of acytotoxic chemotherapy drug.
	• CCA does not usually compensate when billed without an FDA-approved or an off-label recommended indication.
	• CCA limits coverage to one unit per date of service unless the diagnosis is mobilization of peripheral blood progenitor cells prior to autologous stem cell transplantation when billed by any provider.
	• CCA limits coverage to two units when billed by any provider.
	• CCA will not usually compensate when billed morethan once every 12 days by any provider and the diagnosis is any of the following:
	  ○ Chemotherapy-induced neutropenia
	  ○ Mobilization of peripheral blood progenitor cells prior to autologous stem cell transplantation
	  ○ Post-peripheral blood progenitor cell transplant supportive care.
	  ○ CCA will not usually compensate when billed and the diagnosis on the claim is chemotherapy-induced neutropenia, and a diagnosis of a neoplasm is not also present.

Drug	Policy Description

Infliximab	**Code(s) J1745, Q5103, Q5104, Q5121**
	• CCA does not usually compensate for the chemotherapy administration, IV infusion technique, for the first hour unless the chemotherapy administration, IV infusion technique, each additional hour has been billed for the same date of service
	• CCA limits to the following when billed by a provider:
	  ○ Once every 6 days
	  ○ Once every 12 days with the diagnosis of an FDA-approved or an off-label recommended indication
	• CCA limits to 80 units per date of service if the diagnosis on the claim is Crohn's disease, rheumatoid arthritis or ulcerative colitis, and infliximab has not been billed in the past year
	• CCA limits units per date of service if the diagnosis on the claim is ankylosing spondylitis, Behcet's syndrome, hidradenitis suppurativa, plaque psoriasis, psoriatic arthritis, pyoderma gangrenosum with inflammatory bowel disease, reactive arthritis, SAPHO syndrome, sarcoidosis, or Takayasu's disease.
	• CCA limits to 570 combined units within a 26-week period when billed by any provider and the diagnosis is any of the following:
	  ○ Early synovitis in rheumatoid arthritis
	  ○ Plaque psoriasis
	  ○ Psoriatic arthritis
	  ○ Pyoderma gangrenosum with inflammatory bowel disease
	• CCA will not usually compensate if billed more than five times every 26 weeks by any provider and the diagnosis is any of the following:
	  ○ Adult regional enteritis (Crohn's disease)
	  ○ Adult ulcerative colitis
	  ○ Early synovitis in rheumatoid arthritis
	  ○ Plaque psoriasis
	  ○ Psoriatic arthritis

Drug	Policy Description
Rituximab	**Code(s) J9312, Q5115, Q5119, Q5123** • CCA does not usually compensate for intravenous push chemotherapy administration when billed with rituximab unless another drug administered by chemotherapy administration has been billed for the same date of service. • CCA does not usually compensate for chemotherapy administration, IV infusion technique, for the first hour when billed with rituximab unless chemotherapy administration, IVinfusion technique, each additional hour has been billed for the same date of service • CCA does not usually compensate for rituximab when billed with a diagnosis of chronic graft-versus-host disease and a diagnosis of complications of transplanted stem cells is not also present. • CCA does not usually compensate for rituximab when billed by any provider more than once per six days unless the diagnosis is: o AIDS-related B-cell lymphoma o Chronic lymphocytic leukemia o Non-Hodgkin's lymphoma o Evan's syndrome o Malignant ascites in advanced low-grade non-Hodgkin's lymphoma Waldenström's macroglobulinemia o Burkitt-type acute lymphoblastic leukemia (ALL)Lymphoma • CCA does not usually compensate for rituximab when billed more than one visits every two weeks by any provider for adiagnosis of: o Primary Sjögren's syndrome o Relapsing-remitting multiple sclerosis o Rheumatoid arthritis • CCA will not usually compensate for rituximab when billed by any provider more than 12 times in a patient lifetime and the diagnosis is chronic lymphocytic leukemia, hairy cell leukemia, large B-cell lymphoma, or mantle cell lymphoma.

Drug	Policy Description

Trastuzumab	**Code(s) J9355, Q5112, Q5113, Q5114, Q5116, Q5117**
	• CCA does not usually compensate if billed without an FDA-approved indication or an approved off-labeled indication.
	• CCA does not usually compensate for intravenous push chemotherapy administration when billed unless another drug administered by chemotherapy administration has been billed for the same date of service
	• CCA limits coverage if billed more than once every 12 days by any provider and the diagnosis is esophageal and gastroesophageal junction adenocarcinoma or gastric cancer.
	• CCA limits to the following when billed by any provider:
	  ○ 91 combined units per date of service
	  ○ One unit if billed and no other drug administered by chemotherapy administration has been billed
	• CCA will limit to 762 combined units every 26 weeks by any provider and the diagnosis is esophageal cancer, esophagogastric junction cancer, gastric cancer, or HER2- positive breast cancer.
	• CCA will not usually compensate when billed by any provider more than once per week and the diagnosis is HER2-positive breast cancer or leptomeningeal metastases in HER2-positive breast cancer.

RELATED SERVICE POLICIES:

National Drug Code Requirements

DISCLAIMER:

As every claim is unique, the use of this policy is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to patient eligibility and benefits on the date of service, coordination of benefits, referral/authorization, and utilization management guidelines when applicable and adherence to CCA policies and procedures and claims editing logic. CCA has the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in this payment policy. If such an audit determines that your office/facility did not comply with this payment policy, CCA has the right to expect your office/facility to refund all payments related to non-compliance.

REFERENCES:

CMS Billing Guide

Commonwealth Care Alliance

Mass Health Provider Regulations

Medicare Claims Processing Manual 100-04 Ch 17

Payment Policies:
Massachusetts / Rhode Island

Provider Manuals:
Massachusetts / Rhode Island

Prior Authorization Forms:
Massachusetts / Rhode Island

POLICY TIMELINE DETAILS

1. July 2020 drafted
2. Effective 12/01/2020
3. Updated 07/02/2021: Added two new biosimilars: Nyvepria (pegfilgrastim-apgf), Q5122 and Riabni (rituximab-arrx), Q5123; Added Epoetin Alfa, J0885 and Q5106
4. Revised October 2021; added MAPD