Department:	Utilization Management	**Original Approval:**	08/10/2018
Policy #:	PM148	**Last Approval:**	07/11/2019
Title:	Granisetron extended-release (Sustol®)		
Approved By:	UM Pharmacy Subcommittee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Granisetron extended-release (Sustol®) for intravenous use: History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Age -Prescribed by or in consultation with oncologist -Labs/diagnostics - Medication list (current and past) to include start and end dates of previous trials for all chemotherapy and anti-nausea therapies.

BACKGROUND

SUSTOL is a serotonin-3 (5-HT3) receptor antagonist indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

DEFINITIONS

Failure is defined as two or more documented episodes of vomiting attributed to the current chemotherapy regimen

Highly emetogenic chemotherapy (HEC): Carboplatin, Carmustine, Cisplatin, Cyclophosphamide, Dacarbazine, Doxorubicin, Epirubicin, Ifosfamide, Mechlorethamine, Streptozocin

The following chemotherapy can be considered HEC in certain patients: Dactinomycin Daunorubicin Irinotecan Methotrexate > 250mg/m2 Oxaliplatin Trabectedin

The following regimen can be considered HEC: FOLFOX

Medicaid Members	***Continue to criteria for approval below.***
Medicare Members	***Step-utilization of Part D drugs not required.***

INDICATIONS/CRITERIA

Coverage of Sustol injection is recommended in those who meet one of the following criteria:

FDA-Approved Indication: **Prevention of Chemotherapy-induced nausea and vomiting (CINV)**

Criteria *Patient must meet the following criteria* **(A, B, C, and D or E and F**

A. Patient must be at least 18 years of age; AND
B. Must be administered in combination with dexamethasone; AND
C. Patient is receiving highly emetogenic chemotherapy (HEC); AND
D. Patient has failed palonosetron while receiving the current chemotherapy regimen; OR
E. Patient is receiving a regimen that is not considered to be HEC; AND
F. Patient has failed with BOTH of the following while receiving the current chemotherapy regimen: Ondansetron (Zofran) or granisetron (Kytril); AND Palonosetron; AND
G. Sustol is NOT covered for: Breakthrough emesis; OR Repeat dosing in multi-day emetogenic chemotherapy regimens

Recommended dosage:

The recommended dosage in adults is 10 mg administered as a single subcutaneous injection at least 30 minutes before the start of emetogenic chemotherapy on Day 1. Do not administer SUSTOL more frequently than once every 7 days. Use of SUSTOL with successive emetogenic chemotherapy cycles for more than 6 months is not recommended.

In patients with moderate renal impairment (Clcr 30-59 mL/min), administer SUSTOL not more frequently than once every 14 days. Avoid SUSTOL in patients with severe renal impairment (CLcr < 30 mL/min).

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

List of Appendices

A. Cockcroft-Gault Equation for Estimating Creatinine Clearance

Citations & References

References	1. SUSTOL [package insert]. Heron Therapeutics, Inc., Redwood City, CA; May 2017 (accessed 6/11/18) 2. NCCN Clinical Practice Guidelines in Oncology for Antiemesis v.3.2018	
CFR	42 CFR § 438.210	
WAC	284-43-2050.	
RCW		
Contract Citation	☒ WAH	AH section 17.3.2.1 General Description of Contracted Services - Pharmacy Benefit and Services - Apple Health Preferred Drug List and Plan Formularies
	☒ IMC	IMC section 16.12.2 General Description of Contracted Services - Pharmacy Benefit and Services - Apple Health Preferred Drug List and Plan Formularies
	☐ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
07/16/2018	New policy	Jennifer Farley, PharmD
08/10/2018	Approval	UM Pharmacy Subcommittee
07/05/2019	Reviewed	Jennifer Farley, PharmD
07/11/2019	Approval	UM Pharmacy Subcommittee

Appendix A: Cockcroft-Gault Equation for Estimating Creatinine Clearance

There are many different methods that can be used to calculate an estimated creatinine clearance (CrCl). The Cockcroft-Gault is one formula that provides an estimate of CrCl using serum creatinine. It is only for adults. This formula tends to overestimate CrCl in obese persons and to underestimate it in those who are lean. The Cockcroft-Gault equation for calculating CrCl is as follows:

$$\text{CrCl in adults } \textbf{(men)} = \frac{(140 \text{ minus age [in years]} \times \text{weight [in kg]})}{(72 \times \text{serum creatinine [in mg/dL]})}$$

For women, multiple the above results by 0.85. The steps, for clarity, are as follows:

1) Subtract the patient's age in years from 140.
2) Multiple by the patient's weight in kg (if weight is in pounds, divide by 2.2 to get kg).
3) Multiple the patient's serum creatinine (in mg/dL) by 72.
4) Divide the total from 2) by the total from 3).
5) If the patient is female, take the total from 4) and multiple by 0.85.

For example, a man who is 55 years of age, who weighs 160 pounds (72.7 kg), and with a serum creatinine 0.9 mg/dL, would have a calculated creatinine clearance of 95 mL/minute. For a woman with these same values, her CrCl would be 81 mL/minute.