System P&T Formulary Management 8/24/2022

Please refer to documents in the agenda packet for additional details

I. System Formulary NEW REQUESTS						
Service Line/Site	Medication	Summary	MUSE Review/ Recommendation	Committee Review, Recommendation/ Endorsement	System P&T (Formulary) Decision on Committee Recommendation/Endorsement	Local P&T Decision on Recommendation
Outpatient infusion, Oncology	**Opdualag (Nivolumab/relatlimab-rmbw)** • 240 mg nivolumab and 80 mg relatlimab per 20 mL single-dose vial • IV infusion	• Requested by NAMED PROVIDER- Hematology/Oncology • FDA-approved for treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma • A first-in-class, fixed-dose immune checkpoint inhibitor that combines Opdivo (nivolumab), a programmed death 1 (PD-1)-blocking antibody, and relatlimab, a lymphocyte-activation gene 3 (*LAG-3*)-blocking antibody, administered as a single intravenous infusion • Supported as 1st line therapy, category 2A recommendations by NCCN guidelines	Recommend to ADD Opdualag (nivolumab/relatlimab-rmbw) to Formulary with the following criteria for use: • Service line: Hematology/Oncology • Formulary location: Outpatient infusion • Service location: Outpatient infusion center • Patient population: Adult, pediatrics 12 years or older • Prior authorization Required: Yes • Restriction/Criteria of use: ○ Diagnosis of Stage III (unresectable) or Stage IV metastatic melanoma ○ No active brain metastases or leptomeningeal metastases ○ No diagnosis of uveal melanoma ○ No active, known, or suspected autoimmune disease ○ Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 ○ No prior systemic therapy in the unresectable or metastatic setting including chemotherapy, immunotherapy, or targeted therapy	System Clinical Coordinators Committee 07/14/2022 (RECOMMEND) System Oncology Subcommittee 07/26/2022 (ENDORSE)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:
Ambulatory	**Varithena (polidocanol)** • 180 mg/18 mL canister • 77.5 mg/7.75 mL canister	• Requested by NAMED PROVIDERand Kenner Interventional Cardiology • FDA-approved for the treatment of incompetent great saphenous veins,	Recommend to ADD Varithena (polidocanol) IV injectable foam to Formulary with the following criteria for use: • Service Line: All • Formulary Location: Ambulatory	System Clinical Coordinators Committee 06/08/2022 (RECOMMEND)	☐ Approve ☐ Deny ☒ **Table for further discussion** Comments: **Tabled, pending more information on why**	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain)

	• IV injectable foam, using ultrasound guidance	accessory saphenous veins, and visible varicosities of great saphenous vein (GSV) system above and below the knee • Current practice at facility: ○ Small veins: Asclera (polidocanol, IV solution) for veins ≤ 3 mm (Varithena used for both small and large vein (average up to 8.7 mm)) ○ Large veins: laser therapy (disadvantage: patient discomfort, length of procedure) – requesting to change Varithena therapy • Varithena provides more consistent, cohesive and stable foam size than physician-compounded polidocanol foam • High cost • Store in a flammable safety cabinet due to the pressurized oxygen component, which can cause or intensify fire/explode if heated	• Service location: Ambulatory clinics, procedural area • Patient Population: Adults 18 and older • Prior Authorization Required: Yes • Restriction/Criteria of Use: ○ Provider trained/certified on use of Varithena (training provided by Boston Scientific company) ○ Veins > 3 mm in diameter ○ Trial and failure, intolerance or contraindication to Asclera for the treatment of varicose vein ≤ 3 mm in diameter *Note:* MUSE to update the SOP: Handling of Corrosive and Flammable Medications and Chemicals in Clinics, to include Varithena and its use in procedural areas	System Ambulatory Subcommittee 07/21/2022 (ENDORSE) System Operations 07/26/2022 (RECOMMEND)	**provider training is needed and how certification is monitored and verified, whether it is through Boston Scientific or facility** Committee members voiced concerns and questioned the manufacturers (Boston Scientific) requirement of providers to be trained for a minimum of 3 procedures, documentation/certification of completion of training and record keeping. Boston Scientific stated they do not have a database with documentation and may not be able to supply the documentation. J. Chou mentioned this is not a REMS drug, there's no FDA mandate on credentialing. This is a manufacturers self-imposed requirement. The ask of the committee is to gather more information on why the manufacturer is requiring the training and record keeping.	Comments:

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II. System Formulary CHANGE or LINE EXTENSION						
Service Line	Medication	Summary	Recommendation	Committee Review	System P&T (Formulary) Decision on Committee Recommendation/Endorsement	Local P&T Decision on Recommendation

Emergency department, Observation units	**Dalvance (dalbavancin)**
	• IV infusion
		• Requested by System ASP
		• FDA-approved for the treatment of adult and pediatric patients with acute bacterial skin and soft tissue infections caused by susceptible isolates of the several gram-positive microorganisms
		• Current status: dalbavancin is available for outpatient infusion suites
		• Positive reimbursement if given in outpatient areas, including EDs and observation units
		• Decrease inpatient admissions: identify and prescribe dalbavancin to stable patients with acute bacterial skin and skin structure infections who comes to EDs
		• Pilot at Facility
			Recommend adding dalbavancin to formulary medication lists, with the following restrictions:
			• Dalbavancin order set is only available to order via an order set restricted to:
			  ○ Patient location: ED, observation units
			  ○ Service line: ED, internal medicine, and ID
			• ID consult is not needed
			• Administration in inpatient floors/units is not allowed
			
			Recommend updating dalbavancin ORDER SET:
			• Remove 500 mg and 1,000 mg dose buttons
			• Keep 1,500 mg dose button (do not lock dose)
				System Clinical Coordinators Committee 08/01/2022 (RECOMMEND)	☒ **Approve**
					☐ Deny
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					Comments:
						☐ Stock
						☐ Not Stock
						☐ Table for further discussion
						☐ Appeal decision (explain)
						
						Comments:

Emergency department	**Avastin (bevacizumab)** • Intravitreal injection	• Requested by NAMED PROVIDER- Ophthalmology • Current status: Avastin intravitreal is available for ambulatory settings • When patients present in the ED with urgent	Recommend updating Avastin ORDER SET with the following: • Name: Bevacizumab (Avastin) 2.5mg/0.1mL ophthalmic injection • Dose button (no change): 1.25mg, 2.5mg • Route button: add intravitreal • Frequency: Once (for ED)	System Clinical Coordinators Committee 07/18/2022 (RECOMMEND)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:

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		neovascular changes, which is an emergent scenario that risks patient blindness, there is a need for prompt treatment with Avastin	• ADD 503B Leiter's Avastin (bevacizumab) 2.5 mg/0.1 mL ophthalmic syringe NDC to Avastin order set, designate as preferred. • Add Avastin order set to central med list, allow pharmacy to order appropriately, upon request. Provider will need to call pharmacy to place order			
Inpatient	**Peritoneal dialysis (PD) solution**	• Requested by named provider • Dianeal PD with Additives ORDER SET does not specify the base fluid (calcium/glucose concentrations) on the production label • inpatient pharmacy cannot verify if the correct dialysate bag was delivered by nursing staff to the IV room for adding medications	Recommend updating order set with the following: • Change order set name: "Dianeal solution with Additives" to "Peritoneal Dialysis Solution with Additives" • Require a base fluid selection: include all 8 commercially available options from Baxter and Fresenius • Update associated order sets *Note:* Standardization project of PD solution product purchased by pharmacy for addition of medications and workflow is on-going.	System Clinical Coordinators Committee 07/14/2022 (RECOMMEND)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:
Inpatient	**Sodium citrate 4%** • Catheter lock	• Requested by named provider • Utilize sodium citrate 4% catheter locks in patients with suspected/confirmed heparin-induced thrombocytopenia (HIT) or patient's needing an alternative anticoagulation catheter lock than heparin due to religious reasons as heparin contains porcine byproducts	Recommend to ADD sodium citrate 4% syringe for catheter lock to formulary: • Order set name: sodium citrate 4% (40 mg/mL) syringe (catheter lock) • Dose Button(s): 3 mL (default), 6 mL, 9 mL • Administration instructions: For hemodialysis catheter lock, 3 mL per catheter lock • Order defaults: route - intra-catheter, frequency - daily PRN, PRN reason - HD catheter lock, dispense code - IV syringe • NDCs under order set: QuVA syringe (default), SCA syringe, premixed bag	System Clinical Coordinators Committee 07/14/2022 (RECOMMEND)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:

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Procedural areas, Inpatient	**Bleomycin** • Intrapleural	• Requested by named provider • Use for the treatment of malignant pleural effusion (FDA-approved indication) • Current status: there is no order set available to order bleomycin intrapleural • Instill bleomycin into the pleural space via chest tube, dwell for 4 hours, and suction • Dispose the removed fluid with residual bleomycin in black hazardous container	Recommend building a bleomycin ORDER SET for intrapleural to be ordered via a therapy plan: • Order set name: bleomycin 60 units in 0.9% sodium chloride (INTRAPLEURAL) • Route locked to intrapleural • Dose is locked to 60 units • Administration instructions: Not for IV use. For intrapleural administration only • Dispense product: 50 mL syringe • Prep comments: please attach an auxiliary label "Not for IV use" to the compounded syringe	System Clinical Coordinators Committee 07/25/2022 (RECOMMEND) Discussed at System Operations 07/26/2022: • Request Paul to have some documents about safety and handling of bleomycin intrapleural	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:
Procedural area	**Methylene blue** • IV infusion	• Requested by named provider • Use for visualization of parathyroid glands prior to parathyroidectomy	Recommend creating an ORDER SET: • Order set name: methylene blue in 500 mL D5W IVPB (for parathyroid glands visualization) • Dose buttons: 5 mg/kg, 7 mg/kg – requesting to populate patient specific dose mg in the ORDER SET • Volume button: 500 mL • Fluid: dextrose 5% • Infusion time button: 60 minutes • Add an indication box: Visualization of parathyroid glands prior to parathyroidectomy	System Clinical Coordinators Committee 07/18/2022 (RECOMMEND)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:

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Inpatient	**Sodium chloride 3% HYPERTONIC bolus**
	
	Sodium chloride 2% HYPERTONIC bolus
		• Requested by named provider
		• The Neurocritical Care Society Cerebral Edema guidelines suggest utilizing hypertonic sodium chloride boluses over continuous IV infusions for the management of elevated intracranial pressure
		• Current status:
		  ○ No order set built out in EHR for sodium chloride 2% and 3% boluses
		Any rate > 150 mL/hr exceeds Alaris pump guardrails, requiring to be run on basic infusion
			Recommend creating order sets for hypertonic sodium chloride boluses:
			• Order set Names:
			  ○ Sodium chloride 3% HYPERTONIC bolus
			  ○ Sodium chloride 2% HYPERTONIC bolus
			Searching synonyms: Request EHR to populate these records when providers search sodium chloride (even without hypertonic) but not normal saline
			• Dose, frequency defaults: 250 mL once over 1 hour
				System Clinical Coordinators Committee 08/01/2022 (RECOMMEND)	☒ **Approve**
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						☐ Appeal decision (explain)
						Comments:

Inpatient	**Methocarbamol** • IVPB	• Requested by named provider • Current status: Many providers are not aware of max dose/duration provided by package insert for IV methocarbamol: max dose of 3 g/day for no more than 3 consecutive days except in the treatment of tetanus. Some patients have received IV methocarbamol for > 3 consecutive days inpatient.	Recommend updating the methocarbamol order set: • Max duration = 72 hours/3 days to be built in the background. Provider has to put number of doses in the order. • Add admin instructions: Administer IV while in recumbent position. Maintain position for at least 10-15 minutes following infusion. • Update associated order sets	System Clinical Coordinators Committee 08/01/2022 (RECOMMEND)	☒ **Approve** ☐ Deny ☐ Table for further discussion Comments:	☐ Stock ☐ Not Stock ☐ Table for further discussion ☐ Appeal decision (explain) Comments:

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Note: Please bring the monthly Formulary Management agenda, System P&T Formulary Executive Summary, and final System P&T Committee Minutes to your local P&T for review and discussion. If your local P&T Committee decision does not align with System P&T, appeals may be submitted to Formulary Management Team. The next System P&T meeting is 10/26/2022. A physician representative must be present to discuss the appeal. Please send the name of the representative and the reason for appeal to the Formulary Management Team by 9/23/2022.