HOUSTON Methodist LEADING MEDICINE

HOUSTON METHODIST
PHARMACY & THERAPEUTICS NEWS
December 2025

FORMULARY UPDATES

Laura M. Blackburn, PharmD

The following medications and classes were reviewed for formulary status

Medication	Formulary Updates
Fibrinogen concentrate inj (Fibryga®)	**Formulary Action:** Added to formulary **Category:** Blood product derivative **Indication:** Fibrinogen deficiency **Restrictions:** ⇒ **Specialty:** Hematology, OB/GYN, critical care, or cardiac surgery/anesthesia physicians ⇒ **Indication:** management of congenital or acquired fibrinogen deficiency **Rationale:** FDA-approved for acquired fibrinogen deficiency, operational and financial advantages over RiaSTAP®
Pegfilgrastim-cbqv (Udenyca® OnBody Injector)	**Formulary Action:** Added to formulary **Category:** Colony stimulating factor **Indication:** Chemotherapy-induced neutropenia, prevention **Restrictions:** ⇒ **Care setting:** outpatient with prior financial approval **Rationale:** Financial advantages over Neulasta® OnPro
Glycerin Liquid Suppository (PediaLax®)	**Formulary Action:** Added to formulary **Category:** Osmotic laxative **Indication:** Constipation **Restrictions:** ⇒ **Specialty:** Neonatal, pediatrics **Rationale:** Ease of dosing in neonates compared to solid
Pembrolizumab and berahyaluronidase (Keytruda QLEX™)	**Formulary Action:** Added to formulary **Category:** Antineoplastic agent **Indication:** Many **Restrictions:** ⇒ **Specialty:** Hematology, OB/GYN, critical care, or cardiac surgery/anesthesia physicians ⇒ **Indication:** management of congenital or acquired fibrinogen deficiency ⇒ **Care setting:** outpatient with prior financial approval **Rationale:** Operational advantage by reducing infusion chair time, increasing scheduling flexibility and patient convenience

Continued on page 2

To request a medication for

The *Pharmacy & Therapeutics News* is dedicated to providing the most current information regarding medication-use policy and formulary issues. Each issue details recently approved actions from the system P&T committee as well as relevant patient safety, pharmacotherapy and drug distribution updates. Entity representatives to the system P&T committee structure can be found here.

Therapeutic Interchange Updates

The following therapeutic interchanges were reviewed and approved.

- **RXMEDTI 111 Therapeutic Interchange Oral Calcium Channel Blockers**

⇒ Triennial review, formulary preferences updated

⇒ Formulary dihydropyridines: amlodipine, nimodipine, nifedipine IR/ER

⇒ Formulary non-dihydropyridines: diltiazem tablet, diltiazem CD ER 24-H capsule, verapamil tablet, verapamil ER tablet

- **RXMEDTI 123 Therapeutic Interchange Short and Long-acting Granulocyte Colony Stimulating Factors (G-CSF)**

⇒ Triennial review, formulary preferences updated

⇒ Formulary short-acting GCSF: tbo-filgrastim (Granix®)

⇒ Formulary long-acting, delayed injection GCSF: Pegfilgrastim-cbqv (Udenyca® OnBody Injector)

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FORMULARY UPDATES (continued)

Laura M. Blackburn, PharmD

Medication	Formulary Updates
Fibrinogen concentrate inj (RiaSTAP®)	**Formulary Action:** Non-formulary **Category:** Blood product derivative **Rationale:** Replaced by Fibryga®
Pegfilgrastim (Neulasta® OnPro)	**Formulary Action:** Non-formulary **Category:** Colony stimulating factor **Rationale:** Replaced by Udenyca® OnBody Injector

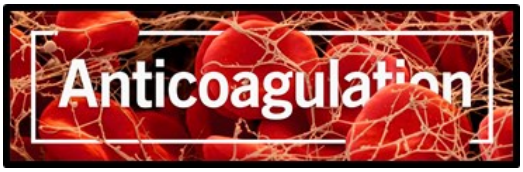
The following therapeutic interchanges were reviewed and approved.

- **RXMEDTI 124 Therapeutic Interchange Topical Antivirals**
  - ⇒ Triennial review, no changes
  - ⇒ Formulary: docosanol (Abreva®) 10% topical cream
- **RXMEDTI 140 Therapeutic Interchange Topical Metronidazole**
  - ⇒ Triennial review, no changes
  - ⇒ Formulary: metronidazole 0.75% topical gel
- **RXMEDTI 154 Therapeutic Interchange HMG CoA Reductase Inhibitors**
  - ⇒ Triennial review
    - ∗ Ezetimibe-simvastatin (Vytorin®) designated as non-formulary and added to therapeutic interchange table
  - ⇒ Formulary: atorvastatin (Lipitor®), rosuvastatin (Crestor®), and pravastatin (Pravachol®)
- **RXMEDTI 155 Therapeutic Interchange Omega-3 Fatty Acids**
  - ⇒ Triennial review, no changes
  - ⇒ Formulary: Omega-3 acid ethyl esters

The following policy was updated and approved.

- **System_RXP&T 116 Preparation of Microbial Vector Therapies**
  - ⇒ Microbial vector therapies are a biohazard and require varying levels of safety precautions (biosafety levels) to reduce the risk of exposure and contamination. The document establishes standard operating procedures (SOPs) to minimize risk of exposure to healthcare personnel and the work environment when handling microbial vector therapies.
  - ⇒ Updates included the recent formulary additions of nogapendekin alfa inkicept-pmln (Anktiva®) and nadofaragene firadenovic-vncg (Adstiladrin®)

ANTICOAGULATION COMMITTEE



Michael Sirimaturos, PharmD

Andexanet alfa (Andexxa®) Removed from the US Market

On Monday, December 22, 2025, all manufacturing, marketing, and sales of andexanet alfa (Andexxa®) in the United States was discontinued by AstraZeneca, and accordingly, Houston Methodist removed andexanet alfa from Epic ordering including removal from the below Epic Order Sets. Pre-approved alternative agents to andexanet alfa remain available in the order sets, and providers attempting to order andexanet alfa will continue to be guided to the appropriate order sets despite the drug no longer being available to ensure correct ordering of alternative agents through the approved order sets.

- Reversal for anticoagulant-induced life-threatening bleeding
- Reversal of anticoagulation prior to emergent procedure/surgery

Andexanet alfa was granted accelerated approval by the FDA in 2018 as a reversal agent for patients with life-threatening or uncontrolled bleeding due to direct oral factor Xa inhibitors (i.e. apixaban, rivaroxaban, edoxaban). The accelerated approval was based on clinical evidence collected in healthy volunteers and preliminary data in patients experiencing life-threatening or uncontrolled bleeding. A condition of the FDA's accelerated approval was a requirement of AstraZeneca to conduct a randomized, post-marketing study to verify and describe the clinical benefit of andexanet alfa.

The ANNEXA-I study, planned in collaboration with the FDA and published in May 2024, was a randomized, open-label, phase IV study designed to provide confirmatory evidence of hemostasis in order to confer traditional approval and verify the clinical benefit of the therapy. ANNEXA-I demonstrated mixed results including significant reductions in hematoma expansion in patients with intracerebral hemorrhage (ICH) due to factor Xa inhibitors, but the results failed to predict longer-term benefit and demonstrated a significant increased risk of thrombotic events including ischemic stroke (7% vs. 2%) when compared to usual care (i.e. 4-factor PCC, 3-factor PCC, or FEIBA). Based on these findings, the FDA concluded that the risks of andexanet alfa outweighed the benefits. AstraZeneca voluntarily withdrew the biologics license application needed for full approval and decided to halt manufacturing and commercial sales of the product in the United States.

Information regarding the change in availability of andexanet alfa was provided by email to frequent users and the following committee members the week of December 15, 2025: System Anticoagulation Committee, ED Council, Stroke Coordinators Council, Critical Care CMPI, and the CV Surgery and Neurology Service Line.

ISMP UPDATES

Mary Soliman, PharmD

ISMP has noted trends amongst healthcare systems they have visited and the following are noted in [ISMP Medication Safety Alert Acute Care August issue]

We continue our series highlighting these themes and sharing Houston Methodist's work to address the practice gaps.

Theme #4: Opioid Status Management

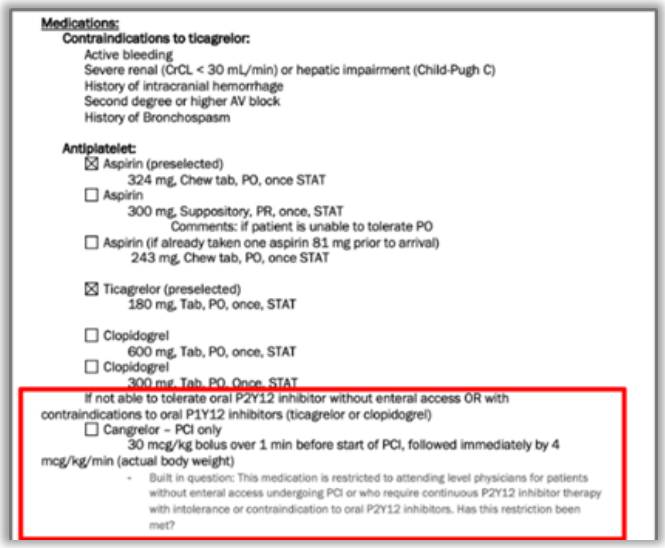
Opioid management and utilization is a vital step towards safety. Lack of clarity regarding "Opioid Naive vs Tolerant" and practitioner's role in pain management as well as education have been noted along with lack of documentation of opioid status or risk for opioid induced respiratory depression. At HM opioid status and high risk for opioid induced respiratory depression are assessed & documented. Furthermore opioid status and type of pain assessed & documented before long-acting opioids prescribed. Other safe guards include defaulting order entry to lowest initial starting dose/frequency when initiating long-acting agents and CDS which alert when LOA dose adjustments needed for age, renal/hepatic function, other sedating meds.

MEDSAFETY UPDATES

Mary Soliman, PharmD

Adult STEMI ED Order Panel

To ensure a smooth transition from the ED to the Cath Lab, an Adult STEMI Order Panel was approved to ensure appropriate antiplatelet and anticoagulation therapy.


Medications:
Contraindications to ticagrelor:
Active bleeding
Severe renal (CrCL < 30 mL/min) or hepatic impairment (Child-Pugh C)
History of intracranial hemorrhage
Second degree or higher AV block
History of Bronchospasm

Antiplatelet:
☒ Aspirin (preselected)
324 mg, Chew tab, PO, once STAT
☐ Aspirin
300 mg, Suppository, PR, once, STAT
Comments: if patient is unable to tolerate PO
☐ Aspirin (if already taken one aspirin 81 mg prior to arrival)
243 mg, Chew tab, PO, once STAT

☒ Ticagrelor (preselected)
180 mg, Tab, PO, once, STAT

☐ Clopidogrel
600 mg, Tab, PO, once, STAT
☐ Clopidogrel
300 mg, Tab, PO, Once, STAT
If not able to tolerate oral P2Y12 inhibitor without enteral access OR with contraindications to oral P1Y12 inhibitors (ticagrelor or clopidogrel)
☐ Cangrelor – PCI only
30 mcg/kg bolus over 1 min before start of PCI, followed immediately by 4 mcg/kg/min (actual body weight)
- Built in question: This medication is restricted to attending level physicians for patients without enteral access undergoing PCI or who require continuous P2Y12 inhibitor therapy with intolerance or contraindication to oral P2Y12 inhibitors. Has this restriction been met?

IMU Electrolyte replacement Order Set

A nurse driven electrolyte replacement in the IMU has been approved mirroring the order set called "ICU/IMU Electrolyte Protocol with NORMAL Magnesium Replacement" (to be used per entity discretion). This will be identical to current ICU Electrolyte Protocol with NORMAL Magnesium Replacement, EXCEPT:

- Add a nursing communication order to allow discontinuation of protocol once patient is no longer ICU/IMU status
- Make AKI statement larger/more visible for nursing (below)

System Methotrexate for Ectopic Pregnancy Policy

To ensure safe administration and handling of Methotrexate for Ectopic Pregnancy a system wide policy addressing the following has been approved: general statement and definitions, safe handling and disposal, contraindications, equipment as well as procedures for specific roles

PCPS 135 Medication Reconciliation Updates

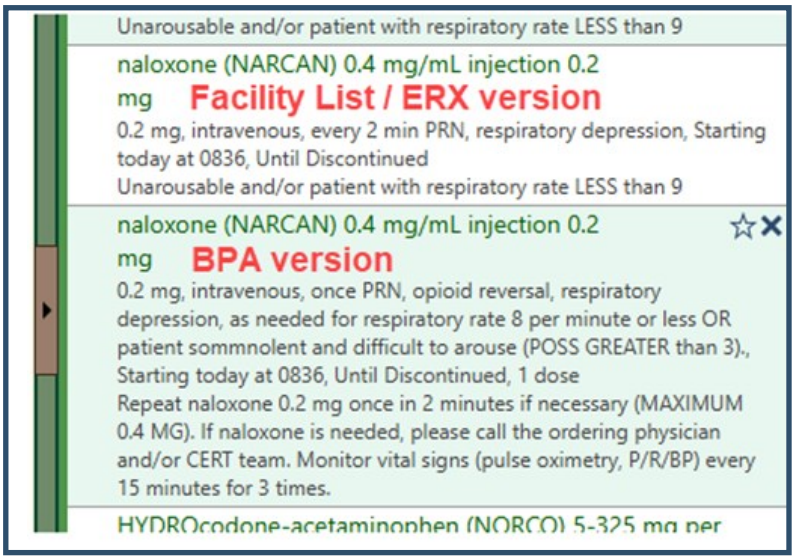
A 2025 systemwide initiative was conducted to enhance medication reconciliation services. An update to PCPS 135: Medication Reconciliation was performed to provide additional clarification of workflow, definition of specific roles and additional guidance for disciplines outside of pharmacy to support completion of the most accurate medication history and reconciliation.

PAIN MANAGEMENT COMMITTEE

Tatjana Ramos, PharmD

Naloxone PRN Dose Orders Updates

To optimize the Nalaxone prescribing and allow for repeat doses for the BPA, the standard naloxone ERX was voted to be set-up to mirror the more comprehensive BPA version and that the maximum number of doses for PRN naloxone be increased from one to two.



System Pain Management Committee Charter Updates

The addition of Prescription Monitoring Prescribing compliance metrics to 2026 SPMC was approved to ensure pharmacists and prescribers check the patient's PMP history before dispensing or prescribing opioids, benzodiazepines, barbiturates, or carisoprodol. This applies to outpatient and discharge prescriptions with the exceptions: of cancer pain, hospice or end-of-life care, palliative care, or medications for opioid use disorder

Project: System Pain Management Committee

Purpose Statement:
A system-wide multidisciplinary group of physicians, pharmacists, nurses, informaticists, and quality and patient safety leaders focused on optimizing pain management therapy across the Houston Methodist system.

Criteria for Success:
Projects considered by the Project Team will address process and outcomes issues related to pain management therapy. Team will include subject matter experts and process owners from across the system. Interventions will be derived from best practices and evidence-based recommendations and designed to achieve standardization across all Houston Methodist entities.

Scope:
The **System Pain Management Committee** will work with HM entity hospitals to optimize pain management therapy for acute, chronic and procedure-related pain across the populations served. Team members will serve as subject matter experts (SMEs) for electronic order set content development, implementation and continuing management, and any associated policies, protocols or standing orders. Projects will examine outcomes of care related to utilization of Pain Project materials and make recommendations on implementation of best practices and safety enhancements relating to pain management.

Risk (Leadership Perspective):
The provision of pain management therapy through the Pain Management Project approved order content is designed to improve safety in nursing assessment and reduce the risk for negative outcomes as due to opioid overuse. Provision of complete nursing administration instructions for selection of pain option improves regulatory compliance.

Estimated Annual Financial Impact:
Financial impact will be calculated and reported as applicable.

Team Leadership:
Chair: Ezekiel Fink, M.D.
Pain Management Pharmacist/Secretary: Tatjana Ramos, PharmD, MPH, BCPS
System Medication Safety Pharmacist: Mary Soliman, PharmD, BCPS

Team Members:
System-wide multidisciplinary group of Physicians, Pharmacists, Nurses Quality and Patient Safety Leaders supported by Clinical Analytics and Information technology.

Anticipated Impact:	High	Mod	Low
Improve Outcomes relating to pain management	●		
Improve Efficiency of use of order sets	●		
Improve Provider/Staff/Patient satisfaction	●		

Key Performance Metrics:	Measurement Tool	Baseline	Target
Safe Use of Opioids (CMS506) eCQM	Epic Dashboards	Entity Compliance between 12-21%	• 10% improvement over self/baseline for each entity • National Average: 15% • State Average: 14%
Inpatient Naloxone Administration	Naloxone Tableau Dashboard	Approximately ~50-60 doses/month Quarterly Patient Evaluation	• Consistent Opioid Induced Respiratory Depression Definition • Identify opportunities for opioid process improvement to prevent ADE. • Mandatory CMS IQR by 2027: Hospital Harm – Opioid-Related Adverse Events (CMS819)
Increase post-pain medication pain assessment compliance	Pain Assessment Tableau Dashboard	78% Systemwide Compliance	• Increase 5% systemwide compliance • Assessment of uptake of patient preference allowance conditions • Assessment of non-opioid post-
Prescription Monitoring Program (PMP) Check on Prescribing	Epic SlicerDicer	Baseline 2025: 23.0% (ALL opioids); 20.8% (DI only)	• Identify opportunities for increased compliance when prescribing opioids

CHEMOTHERAPY STEWARSHIP COMMITTEE

Erika Brown, PharmD

Oncology Treatment Plan Updates

The oncology treatment plan committee met in November to review the therapy, treatment and research plans within Beacon-Epic and the following were approved:

1. Five newly created treatment plans were built: Polatuzumab—CHP, GemOx/Glofitamab, Margetuximab/ Eribulin, Margetuximab/Vinorelbine, and Margetuximab/Gemcitabine.
2. Therapy plans with Risankizumab, ustekinumab, and vendolizumab were reviewed to standardize nursing communication regarding vaccines, standardize orders contained in the hypersensitivity order set, standardize pre-selection of all orders in hypersensitivity orders and nursing orders, and to change the anti-nausea medication from intravenous promethazine to intravenous ondansetron.
3. Treatment plans containing amivantamab were reviewed to standardize home dexamethasone and premedication updates, standardize naming, and standardize provider communication(s) regarding dose and rate depending on patient weight
4. Deactivation of treatment plan margetuximab

Policy Update

System Antineoplastic Nursing Policy (System_PCPS223 Chemotherapy and Antineoplastic Administration)

Current	Future
Varying chemotherapy administration workflows across campuses (differences in handling, PPE, and documentation)	Standardized system-wide procedures for chemotherapy, immunotherapy, and targeted therapy administration
Varying chemotherapy administration education	Standardized oncology education requirements
Limited awareness of USP <800> and NIOSH requirements among frontline staff	Education and annual competency validation for all nurses and pharmacy personnel handling hazardous drugs
Education and updates delivered locally and inconsistently	**Systemwide rollout via PPL-led in-services,** STAT flyer, and policy change alert to ensure consistent messaging.

Benefits of standardization include improving patient safety by reducing variation in practice, supporting nurse mobility between campuses with consistent expectations, enhancing consistency with national standards and accreditation, and providing legal and regulatory protection

Key policy elements

Provider orders (verification, electronic order sets, double-checks), **nursing administration** (competencies, PPE, infusion safety, independent double verification), **patient safety measures** (informed consent, education, monitoring, adverse event management, fertility discussion), **exposure control** (safe handling, spill management, waste disposal), and **competency & training** (annual validation, initial orientation, continuing education).

CHEMOTHERAPY STEWARSHIP COMMITTEE (continued)

Erika Brown, PharmD

Oncology Exception Review Panel (ERP) 2024 Data Review

ERP is a process involving the approval of medications outside of the HM-approved criteria, and it also involves regular monitoring of medication use patterns and reporting of exceptions/deviations from policy. This is particularly relevant in oncology for the purpose to steward the use of highly expensive antineoplastic medications and to recommend alternatives for the most appropriate site of care for treatment.

From the review period of 1/1/2024 to 12/31/2024, daratumumab and immune checkpoint inhibitors (ICIs) comprised approximately 50% of all ERP requests.

Based on literature review and clinical scenarios, the following was approved:

**Revision of ERP criteria for daratumumab and ICIs to include:

1. ICIs can be safely delayed by one cycle for all admitted patients
2. Daratumumab can be approved for inpatient use if the following criteria are present:
   * Acute Kidney Injury (AKI)/cast nephropathy
   * Cardiac Amyloidosis

Lab Window for Carboplatin

For safe administration of a chemotherapy treatment plan, patients are encouraged to get labs up to three days prior to treatment to avoid delay and to address any abnormal lab result. At Houston Methodist, the carboplatin orderable required a serum creatinine value within 72 hours of planned carboplatin administration.

It observed that depending on the patient's treatment schedule, labs drawn three days prior to treatment may fall outside the 72-hour window. To avoid delays on the day of treatment, an extension of that window of time by 12 hours to 84 hours (versus 72 hours) was approved. This change allows patients to receive safe, uninterrupted care even if they had an early-day lab draw three days before.

NEWSLETTER STAFF

Editor-in-Chief: Michael G. Liebl, PharmD

Managing Editor: Laura M. Blackburn, PharmD

2025 System P&T Committee roster is available to view here.