Coalition Prosthetics Working Group Call

11/12/2026

THE COALITION
FOR GOVERNMENT PROCUREMENT

Agenda

- Discussion with Jennifer Martin of Remund Group on Veterans Prosthetics Advancement and Reform Act.
  - Discussion of VA Pharmacy Formulary Program.
  - Is this a viable model for Prosthetics Purchasing.
  - Feedback/Recommendations to Senate VA Committee.
- Feedback to PSAS Update.
  - Contract Additions.
  - Payment Issues.
  - Consignment.

Discussion with Jennifer Martin of Remund Group

- Veterans Prosthetics Advancement and Reform Act
  - Bill would establish a VA-wide Prosthetic Formulary
    - with Input from Veterans and the public
    - Ensure that all items and services included in the Formulary are available at or through all facilities of the Department.
  - The Secretary shall enter into such contracts as the Secretary considers necessary to support the availability of items and services included in the Formulary.
  - The Secretary shall establish a process for clinicians of the Department to request, prescribe, and furnish prosthetic and rehabilitative items and services that are not included on the Formulary when medically necessary.
  - In developing the Formulary, the Secretary shall consider how the approach of the Pharmacy Benefits Management Services of the Department for formulary management and medication safety can be adapted to support the efficient and effective administration of the Formulary.”.

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VA Pharmacy National Formulary Overview for CGP Prosthetics Workgroup

VA National Formulary Terminology

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- Formulary
- Formulary prior authorization local facility (PA-F)
  - May require CFU to be adjudicated at local facility level
  - May be provider restriction (i.e. restricted to hematologists/oncologists)
- Formulary prior authorization national level (PA-N)
  - Requires CFU to be adjudicated at national level
- Non-formulary
  - May require CFU to be adjudicated at local facility level
  - If no nationally approved CFU, then clinical justification must be provided when the medication is ordered, and the local facility will adjudicate

*From an operational perspective, prior authorization with criteria for use and non-formulary with criteria for use involve the same steps in order to request and access the medication**

Evolution of the VA Pharmacy Formulary

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Pre-1990's – each medical center created their own formulary

Early to mid-1990's → local facility formularies were frozen and VISN level formularies were compiled

1997 → VISN level formularies were frozen, and the original VA national formulary was published

VA Formulary Overview

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- VA National Formulary is the sole drug formulary
  - Formulary information publicly available on VA Formulary Advisor: VA Formulary Advisor
- Tiered Copayments (not tied to formulary status)
  - Tier 1: $5 for preferred generics per 30-day supply
  - Tier 2: $8 for non-preferred generics and some over the counter medications per 30-day supply
  - Tier 3: $11 for brand name medications per 30-day supply
    - Roughly 50% of VA beneficiaries are copay exempt due to service connection
- Non-formulary and Prior Authorization Process
  - **ALL FDA approved medications are available within the VA system regardless of formulary status**
  - Every facility must have a system in place to adjudicate non-formulary and prior authorization requests with goal of adjudication within 96 hours for majority of requests

VA Formulary Review Process for New Molecular Entities (NMEs)

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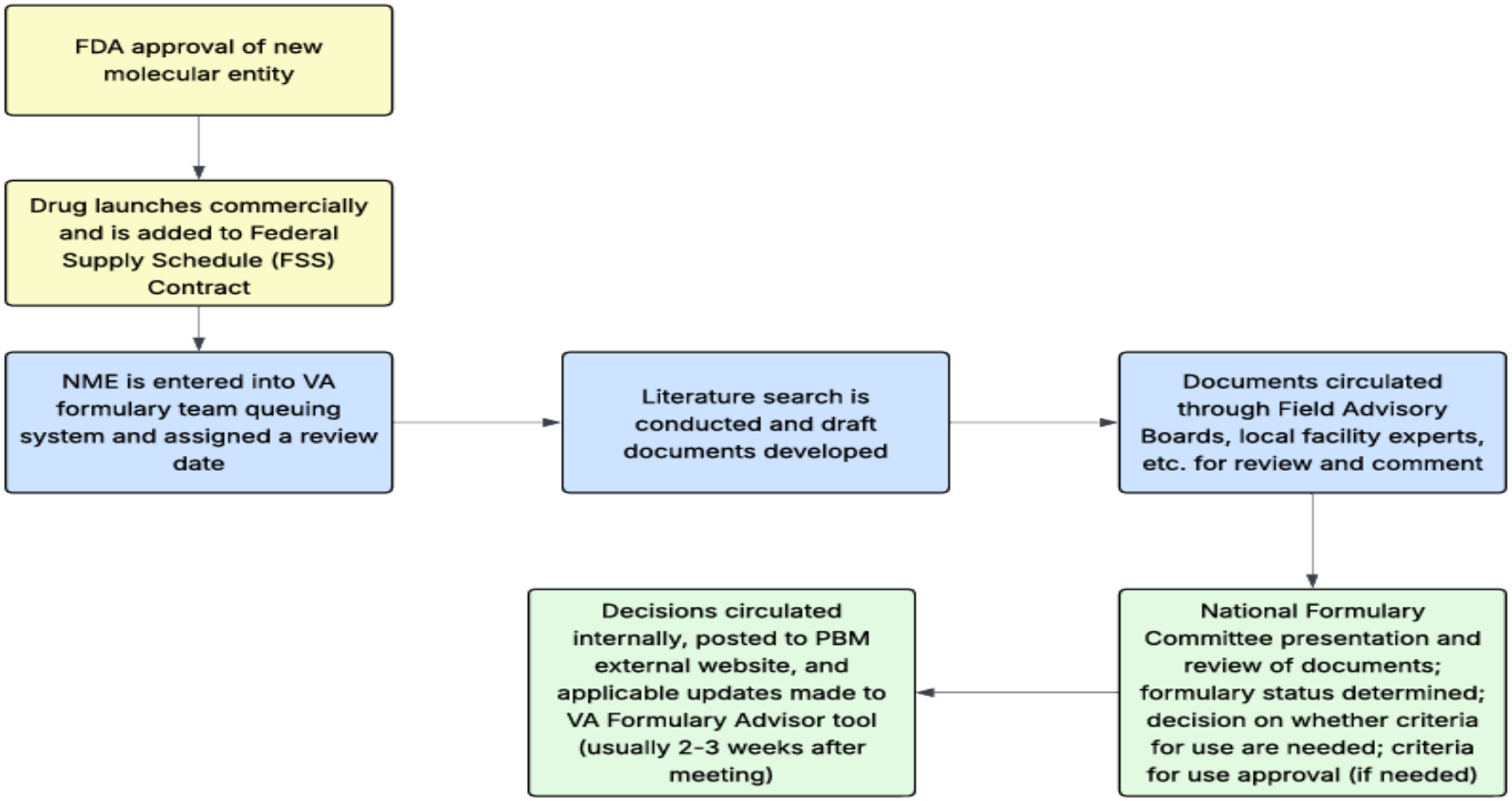

VA Formulary Review Considerations

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- VA National Formulary Committee Membership
  - 18 Veterans Integrated Service Network (VISN) Pharmacist Executives (VPEs)
  - 15 Physicians from different specialties across the VA system
  - 6.5 PBM National Program Managers (develop clinical documents and vote when needed to normalize the number of VPE and physician votes)
  - Other PBM team members (non-voting)
- Meeting cadence
  - Monthly calls
- VA National Formulary Committee utilizes evidence-based formulary review process
  - Safety and efficacy data are primary drivers of review process
  - Cost is deciding factor in cases where safety and efficacy are comparable between drugs in a class/disease space otherwise is last consideration after safety and efficacy have been assessed
  - VA criteria for use inclusion and exclusion tend to mirror clinical trial design and may differ from FDA approved prescribing information

VA Non-Formulary Process

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- Overarching principles outlined in VHA Directive 1108.08 :VHA Formulary Management Process
  - Non-urgent requests must be adjudicated within 96 hours when possible
  - All facilities must have process in place to adjudicate urgent requests

- Local implementation may vary from facility to facility
  - EHR being utilized at site also impacts process flow
  - CCN providers unable to follow traditional non-formulary process flow due to not having access to VHA Electronic Health Record

- Per national trends, somewhere in the range of 80-85% of non-formulary requests are approved at the facility level
  - Solid clinical justification is key to approval

VA Non-Formulary Appeals Process

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- Per VHA Directive 1108.08, every facility must have an appeals process in place for non-formulary requests that are disapproved

- Second-level review is conducted by Medical Facility Pharmacy and Therapeutics Committee Chair

- Provider is advised to supply additional clinical justification when entering an appeal consult versus just sending the same justification that was initially used for original request
  - Appeals data is tracked nationally by PBM
  - Expectation is that appeals will be adjudicated within 96 hours of request

Characteristics of VA National Formulary

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- Generic name and dosage form specific, not product or manufacturer specific
  - Possible due to FDA's rating system of interchangeability with medications
  - All products under a generic name and dosage form roll up into VA product name, then local facility or Consolidated Mail Outpatient Pharmacy determines which product to procure under that listing

- Clinical determinations are made independently of contracting
  - After clinical review, contracting actions may be taken, but always guided by the clinical, not the other way around
  - Public Law 102-585 mandates that all "covered drugs" are added to the Federal Supply Schedule
  - VA has Pharmaceutical Prime Vendor Contract (PPV) which distributes vast majority of contracted pharmaceuticals

Application of Formulary Concept to Prosthetics

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- Is it possible to clinically compare products using objective data in the absence of a rating system such as the FDA AB rating system for pharmaceuticals?
  - In absence of standardized or head-to-head trials, how can a group determine which product is preferred when multiple options?
  - How would patient specific needs to addressed by formulary or contracting (i.e. custom artificial limbs, etc.)?
  - Would the development of a generic list of items that are preferred solve the challenges that this bill is aiming to address?
- Would one committee handle all reviews, or would separate committees be needed for different item categories?
  - Due to breadth of items offered through Prosthetics, would likely need multiple teams of experts to weigh in. Process would be labor intensive and may require significant training to orient committee members.
- If process built for requesting “non-formulary products” in Prosthetics, who will adjudicate those requests?
  - Many items would likely require clinical input outside of Prosthetics personnel
- Currently, Prosthetic items being purchased in multiple ways (MSPV, Prosthetics specific contracts, open market, etc.)
  - Would a formulary structure streamline procurement?

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Questions?????

Discussion with Jennifer Martin of Remund Group

- Discussion of VA Pharmacy Formulary
  - Is this a viable model for Prosthetics Purchasing?
  - Feedback/Recommendations to Senate VA Committee?

Contract Additions

- October 30 VA's Dene Nichols and Nathan Bradley updated contractors on new guidance to be released in mid-Nov 2025 that allows for-
  - Continuous Open Seasons (for some products)
    - New technology line items at any time
    - Products that are part of existing product families already on contract (at any time)
  - 2 Semi Annual Add Periods (for all other products)
    - Contractors would be split into 2 groups (e.g. Group of 15 companies would have add periods 2X per year)
    - Reduces volume of adds per period for VA therefore increasing efficiency
    - More consistent and efficient add periods for industry
  - Further Action on this area requires FAR and Section 8123 overhaul to progress but VA continues to collaborate with industry on process improvements.

Payment Issues

- Still 2 invoices required
  - Prosthetics items paid by Prosthetics (timely per members).
  - Closely Associated Prosthetics Items (CAPI) (i.e., accessories) paid by Logistics (significant delays per members).
  - VA PSAS recommends that any contractors experiencing significant delays with Logistics to contact Audrey Upchurch who can assist.
    - What experiences are members having with payment, what issues are people having? Are there commonalities for the VA?
- Section 8123
  - PSAS confirmed that no changes to Section 8123. However, Office of General Counsel has expressed concerns about applicability of competition requirements.
  - PSAS preparing Section 8123 white paper to VA Secretary.
  - Coalition may want to consider a Section 8123 letter to the VA Secretary.
    - What is interest of the working group on this?

Consignment

- Some contractors have heard from VA facilities that are requiring vendors to provide consignment
- VA PSAS and SAC confirmed that per the SING contract, consignment is optional for vendors
- PSAS will begin conducting SING contract training for VA buyers beginning Jan. 2026
- What interest is there for process improvement deep dive from the Working Group on this?

Conclusion

- Coalition Conference is now in January 14-15
  - Healthcare Day is Day 2, same agenda
  - Coalition looking to set up lunch session with Brian Newbold, VA Senate Committee Staff to discuss legislation
- Orthopedics update
  - Currently PSAS not looking for industry input as they roll out new process.