



Cencora DoD Pharmacy Prime Vendor (PPV) & Understanding the Pharmacy Supply Chain

Aaron Middlekauff, Pharm.D., CAPT, USPHS (ret), SAFFP Treasurer

Feb 2025

Conflict of Interests

Aaron Middlekauff declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.



Learning Objectives

- Name the pharmacy contracts Cencora partners with DoD in delivering
- List the Cencora contacts or resources to assist in facilitating supply chain issues experienced by DoD
- Identify efficiencies and resources extended as a DoD stakeholder

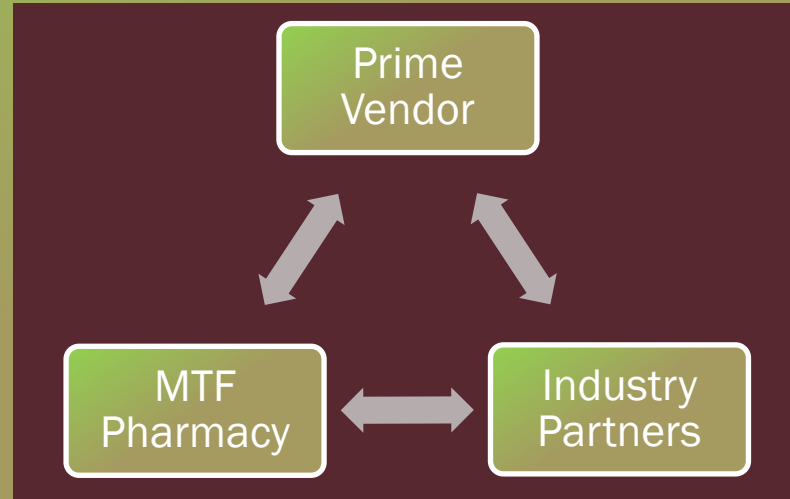


Pharmaceutical Supply Chain



Supply Chain – Obstacles

- Availability
 - Backorder
 - Short Dating
 - Market Spike
 - Weather
 - DC Stock Level
 - Non-Stock Item (NSI)



Usages

- Changing preferred NDC
- New item monthly usage
- Increase or decrease demand
- Discontinued item

- Service@AmerisourceBergen.com
- 877.774.6329



Year End Pre Book

- Email service@amerisourcebergen.com or call 877.774.6329 to request a "Pre Book"
- Place each manufacturer/vendor on a separate PO
- Allow three days for Amerisource Customer Care to get an approval
- When product arrives at the distribution center it is set aside and not added to inventory
- Or place an 1155 drop ship order



Government Services & Solutions Team



Marian Benz

SVP, Government Services & Solutions



Alex Merritt

VP, Government Services & Solutions



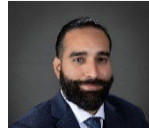
Aaron Middlekauff

VP, Government Services & Solutions



Aaron Adams

Director, Contract Management



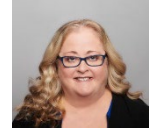
Michael Marquez

Director, Government Account Management, DOD



Jennifer Bennett

Sr. Manager, Government Services & Solutions



Teresa Oakley

Readiness Support, DOD



Yessenia Ramirez

Account Manager, DOD



Sharon Pritchett

Account Manager, DOD



Maureen Kono

Account Manager, DOD



Maria Ramos

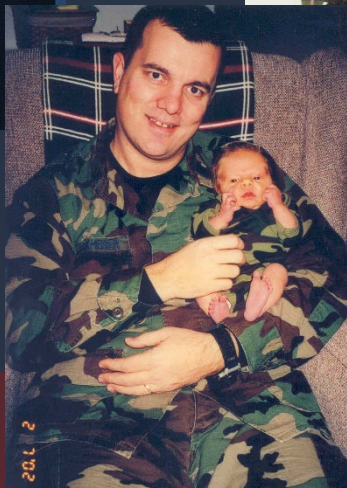
Account Manager, DOD



Stephanie Mitchell

Account Manager, DOD

“Good” ‘ol days...



Cencora is a leading pharmaceutical solutions company centered on improving the health of people and animals around the world



\$250+ billion
revenue

Growth aligned with our customers' long-term success



46,000+ team members

- Diverse expertise all focused on improving global health



1,300+
global
locations

- Delivering a range of services to address specific, local needs



50+ countries
with a local presence

Growing knowledge of market-specific healthcare environments



#11
on the Fortune 500 list

Recognized for breadth and scale

U.S. Enterprise distribution network

50+ total U.S. distribution facilities

Wholesale

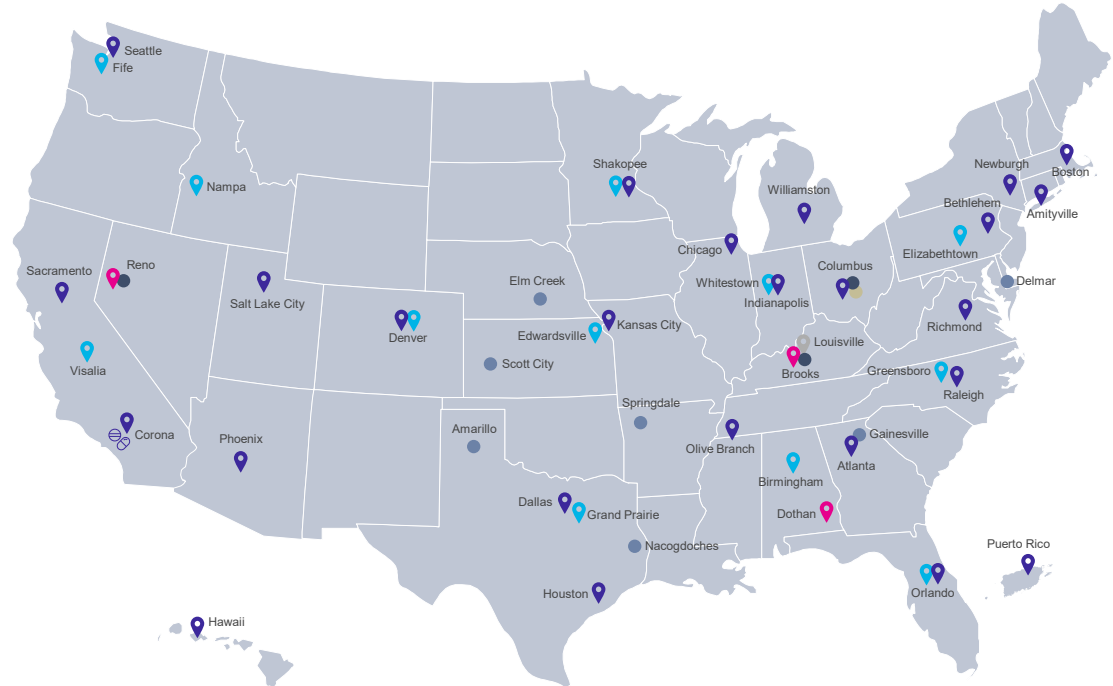
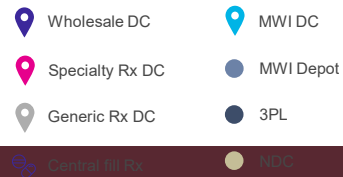
- 25 Wholesale DCs
- 1 National DC
- 1 Generic Rx DC
- 1 Central fill location

Specialty

- 3 Specialty Rx DCs
- 3 3PL facilities

Animal Health

- 12 Animal Health DCs
- 7 Animal Health Depots



DSCSA Update



FDA Grants Exemptions Beyond the Stabilization Period

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ADMINISTRATION

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Waivers and Exemptions Beyond the Stabilization Period

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Drug Supply Chain Security Act (DSCSA)

Drug Supply Chain Security Act Law and Policies

Drug Supply Chain Security Act (DSCSA) Portal in CDER NextGen

[The Drug Supply Chain Security Act \(DSCSA\) Waivers, Exceptions, and Exemptions](#)

[Notify FDA of Illegitimate](#)

FDA Grants Exemption to Connected Trading Partners

FDA is issuing an exemption from the enhanced drug distribution security requirements of section 582 of the FD&C Act for eligible trading partners. This exemption applies to any product transacted by eligible trading partners, which are trading partners who have successfully completed or made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.

This exemption is part of the agency's broader efforts to avoid supply chain disruptions and ensure patients will not face delays in receiving the medicines they need.

FDA is committed to ensuring patient access to medicines and avoiding supply chain disruptions while continuing significant progress toward full implementation of Drug Supply

Content current as of:
10/09/2024

Regulated Product(s)
Drugs

More Information:

[DSCSA Exemptions from Section 582\(g\)\(1\) and Other Requirements of the FD&C Act for Certain Trading Partners](#)

FDA Announces Sector Exemptions

October 9th, 2024



FDA has issued an exemption from the enhanced drug distribution security requirements of section 582 of the FD&C Act for eligible trading partners. This exemption applies to any product transacted by eligible trading partners, which are trading partners who have successfully completed or made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.

- Manufacturers & Repackagers
Exemption Ends:
May 27th, 2025



- Wholesale Distributors
Exemption Ends:
August 27th, 2025



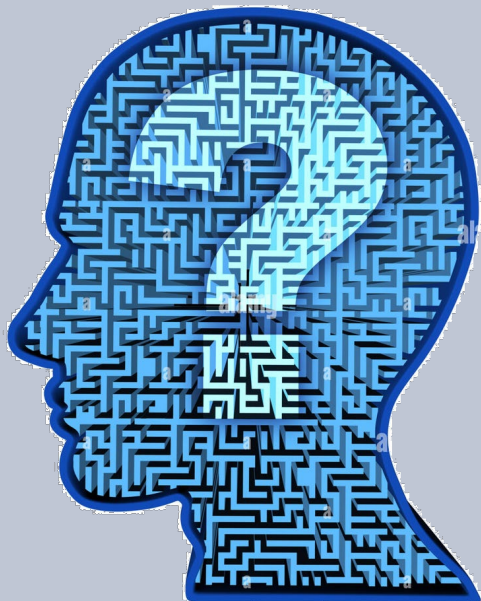
- Dispensers*
Exemption Ends:
November 27th, 2025



*Excludes Small Dispenser Exemption
(November 27th, 2026)

AmerisourceBergen

**What does this mean
for Cencora?**



What are we “thinking”?

- **Manufacturers & Repackagers**
 - DO NOT STOP
 - If a manufacturer is not sending data at all...
 - This exemption does not apply to them
 - They must get their own WEE before 11/27/2024
 - Current Lot Level transaction (ASNs) must still be provided
- **Cencora**
 - WE ARE NOT STOPPING
 - Continue scanning 100%
 - Continue reporting exceptions to manufacturers
 - Continue ramping up customers with EPCIS / training
 - May 27th, 2025 – targeting “Live” with manufacturers

Open Threads

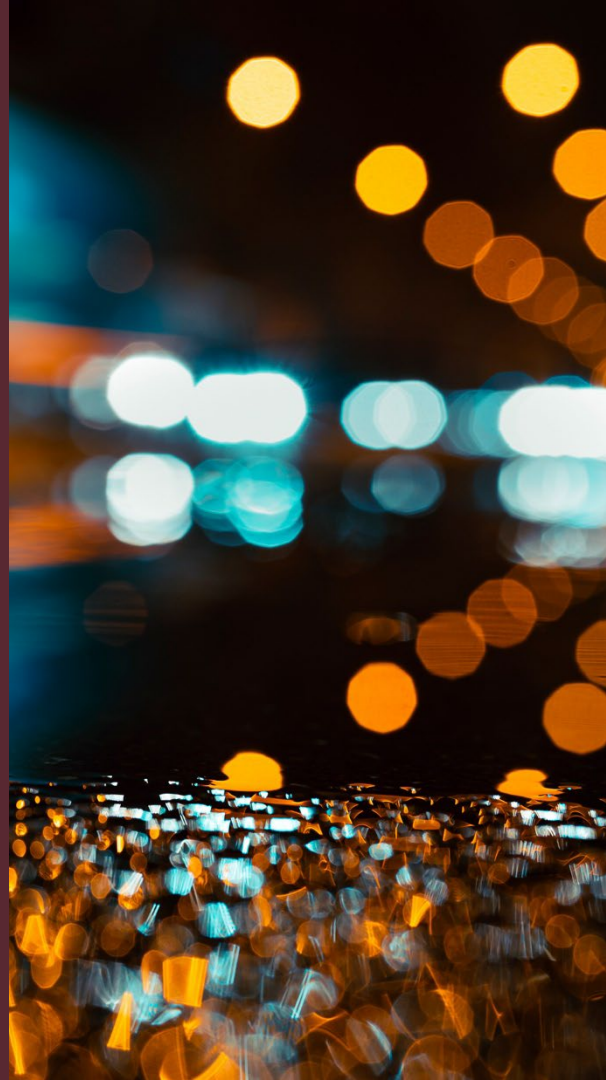


Open Threads

Topic:	Due Date:	Notes:
Cencora's WEE and WEE list.	10/31/2024	<ul style="list-style-type: none">FDA has withdrawn Cencora's WEE due to the exemption extension.COR will no longer be supplying Partners with the WEE NDC list.Will revisit in 2Q25.
Serialized Returns	10/31/2024	<ul style="list-style-type: none">Serialized returns has been delayed until mid-2025 due to the exemption extension.COR to provide additional updates in early 2025 which will lay out training and when the functionality will be available to use.
Drop Shipments	Open	<ul style="list-style-type: none">203 response from 480 MFGs<ul style="list-style-type: none">134 do not do drop ships43 send data today14 will in the near future12 use only a portalWorking with HDA and GS1 to create a standard identifier that all ATPs can use.



Where are we today?



Where are we today?

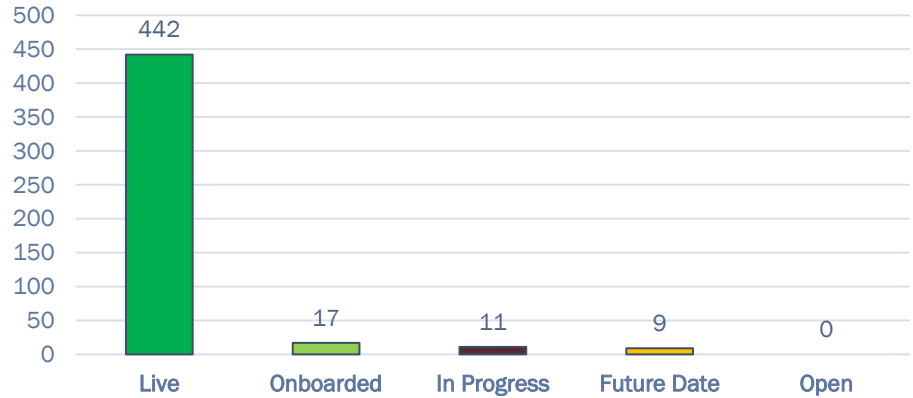
- All Cencora DCs are scanning both inbound and outbound.
 - ✓ *Note that at this moment not all EPCIS messages have 100% of the serial #s as some MFGs are still not sending all the data and we are still using the stabilization period to make enhancements at our DCs.*
- NEW DSCSA report live and available in the 'Reports' section of ABC Order.
- EPCIS files are flowing daily for those customers that have onboarded with Cencora.
- Exploring exceptions with some of the daily EPCIS messages.



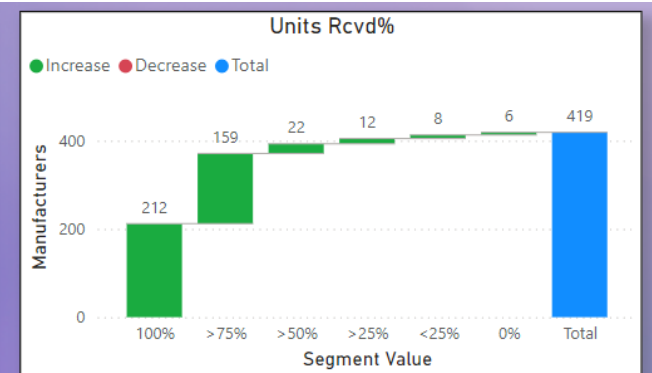
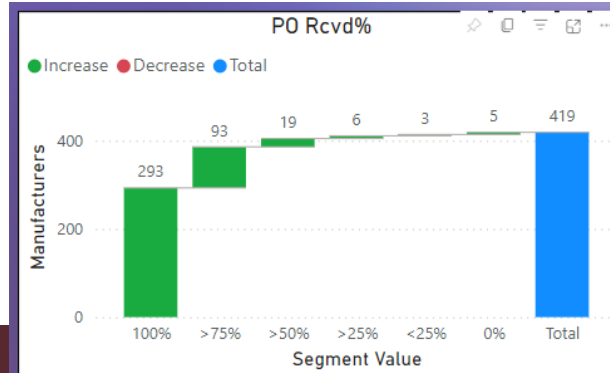
Wholesale Suppliers Status

Supplier EPCIS Status	Supplier Count	% of Total
Live	442	92%
Onboarded	17	4%
In Progress	11	2%
Future Date	9	2%
Open	0	0%
TOTAL	479	100%
TOTAL Connected to Prod	459	96%

Supplier count by EPCIS Status



Live suppliers categorized by % data (POs and Units received) – Last 2 weeks
 - 100% PO's and 100% Units trending higher



MODS EPCIS Dashboard

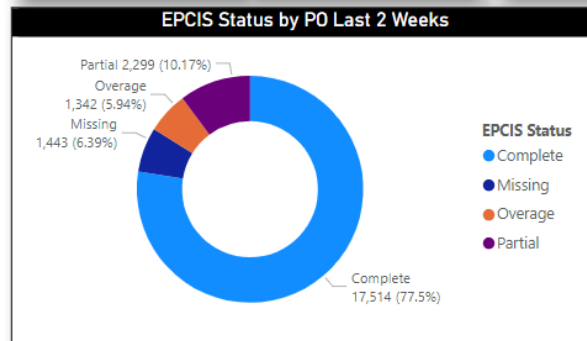
- Recent issues with some supplier causing a dip/stagnation
- Mostly issues attributed to 3PLs and solution providers

Order Performance Last 2 Weeks

PO Serialized Reconciliation	Physical Qty Serialized Reconciliation
94.04%	92.24%

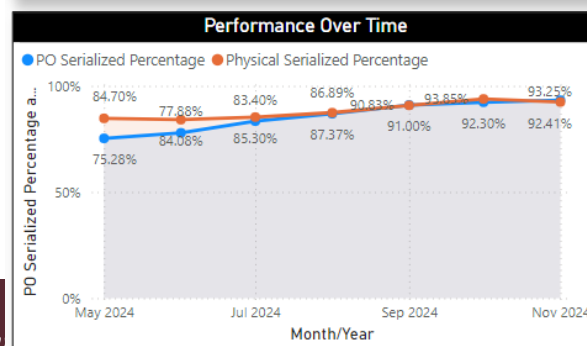
Unique Product Performance Last 2 Weeks

EA GTIN %	PK GTIN %	CS GTIN %
 91.73%	 78.82%	 80.77%



Order Performance by DC Last 2 Weeks

Location Name	PO Rcvd %	Physical Rcvd %	Order Qty Rcvd %
Amityville	92.28%	95.44%	94.11%
Atlanta (Buford)	89.02%	89.02%	88.29%
Bethlehem	94.01%	83.10%	82.76%
Boston (Mansfield)	94.47%	78.73%	78.21%
Brooks	95.27%	97.65%	97.29%
Chicago	93.33%	90.29%	89.49%
Columbus (Lockbourne)	94.25%	87.04%	86.03%
Columbus NDC (Lockbourne)	95.81%	93.59%	91.86%
Corona	93.02%	87.57%	86.33%
Dallas (Roanoke)	94.68%	87.37%	86.79%
Denver	92.71%	91.92%	91.33%
Dothan	92.71%	70.70%	69.99%
Honolulu	95.24%	112.93%	112.30%
Houston	93.37%	91.37%	90.40%
Indianapolis	94.00%	93.14%	91.71%
Kansas City	94.81%	82.14%	81.36%
Louisville	92.11%	92.30%	91.99%
Montclair	94.55%	90.85%	90.32%
Morrisville	94.05%	92.86%	92.39%
Newburg	93.75%	88.85%	87.83%
Olive Branch	94.30%	85.90%	85.38%
Orlando	93.51%	89.61%	89.15%
Phoenix	93.94%	85.94%	85.25%
Puerto Rico	91.64%	93.40%	92.84%
Richmond	93.82%	88.45%	88.03%
Sacramento	94.91%	83.55%	82.78%
Salt Lake City	92.06%	95.48%	95.23%
Seattle Des Moines	93.20%	93.16%	92.33%
Shakopee	94.74%	93.56%	92.16%
Williamston	93.65%	96.15%	95.56%
Total	94.04%	92.24%	90.77%



Improve



What's Next?



What's Next?

- If you would like to receive EPCIS files, please send an email to DSCSA_Customer@cencora.com
- Check the NEW DSCSA report in ABC Order for your orders.
- Continue any cadence calls.
- Review data quality of EPCIS files.
- Start to build out and test the exception process with Account Service in early 2025.



AmerisourceBergen became Cencora

The Cencora logo is displayed in a white rectangular box. The word "cencora" is written in a lowercase, purple, sans-serif font.

What is changing?

- AmerisourceBergen and Alliance Healthcare will become Cencora
- In 2023, the process of adopting a unifying global name and brand will begin

Why are we changing?

- To create a seamless customer and employee experience
- To support our global growth strategy
- To demonstrate differentiated value for the future of healthcare

What can you expect?

- Uninterrupted service
- Communication and transparency as we embark on this transformation
- Unwavering commitment to our purpose

USAMMCE-E RFID Initiative

- Third palletized product with RFID tags received
- All systems “go”
- Data aligned and flowing
- New steady state

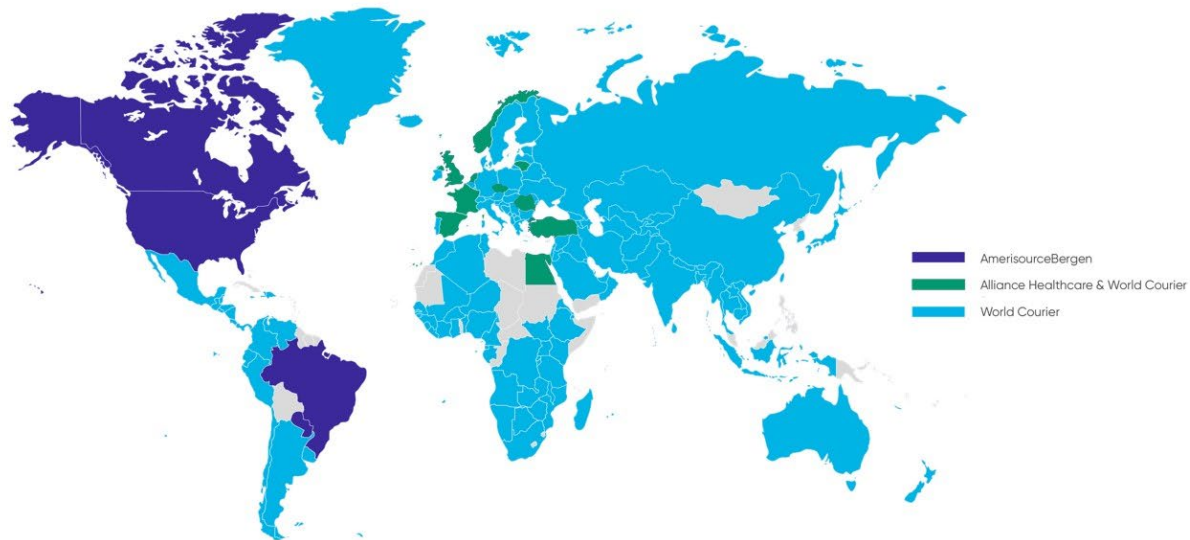


2024-25 COVID Vaccine Update



AB/Alliance Healthcare Global Reach

Our global presence



AB Med Tray RFID Solution

Key advantages for our RFID solution

- Pre-tagged products from AmerisourceBergen can save time and reduce costs
- Mountable touchscreen kiosk and hand-held scanner minimize footprint and improve flexibility for hospital-wide monitoring
- Entire medication tray can be scanned in seconds

Medication tray technology features

- Dedicated mobile application for convenient tray management hospital-wide
- Expiry date and tampered product flagging
- Compatible with all storage cabinets
- Online dashboard with real-time data and insights

cencora

FormularyDecisions® for Healthcare Decision Makers

This presentation was created for Cencora (formerly AmerisourceBergen) sales teams to introduce FormularyDecisions to their customers

Last updated March 23, 2024

2025
2024
2023
2022
2021
2020
2019
2018
2017
2016
2015

cencora

An online platform and product information resource designed exclusively for healthcare decision makers

(HCPM)

FormularyDecisions Pipeline Insights Exclusive Resources P&T Essentials P&T Perspectives

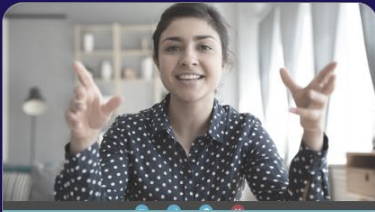
Search Mail Profile Contact Us

Hello! What are you looking for?

Enter Product Name or Disease Area of Interest



KB-103 (beremagene geperpavec)
Product Snapshot
Independently curated product overviews



AMCP PIE Webinar: The Path to HCV Elin
Webinar
Registration Open



KB-103 (beremagene geperpavec)
Product Snapshot
Independently curated product overviews



KB-103 (beremagene geperpavec)
eDossier
Manufacturer's dossier (electronic format)



Complimentary access is available for all eligible HCDMs

Eligibility aligns with the FDA's Guidance on "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities"

HCDMs review scientific and/or technology assessments to make drug or device selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis

HCDMs represent a multitude of private and public organizations



Hospitals



Health
systems



IDNs



PBMs



MCOs

2026/2025

cencora

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FDA-approved and pipeline products*

1 million+

evidence links to scientific resources, including complimentary content exclusively for FormularyDecisions users*



*FormularyDecisions Data on File, 2022

Formulary Decisions

Supporting formulary placement decisions



Access curated pre-approval information, clinical trial summaries, and P&T considerations, created by clinical pharmacists



Review various evidence resources and find research links from leading scientific journals



Request clinical and economic information from numerous biopharma companies



Review national pharmacy and medical coverage data from managed care organizations



Stay up to date on the US biosimilars market landscape, pipeline, and state substitution laws



Conduct P&T reviews using specialized tools

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“**[FormularyDecisions]** has been a great resource for our **Formulary team**. It is much easier to access required Dossiers for drug and class reviews, which includes data unavailable elsewhere (Data on File, models, etc). In addition, it has convenient links to other tools such as ICER reports, formulary kits, articles, etc. — and the pre-approval information helps us plan. It is really nice to be able to go to one place for all of this information.”

— Head of Clinical Pharmacy, Managed Care Organization

Easily manage resources, webinars, and eDossiers in HCDMs' personal FormularyDecisions Inbox





















☰ FormularyDecisions Pipeline Insights Exclusive Resources P&T Essentials P&T Perspectives

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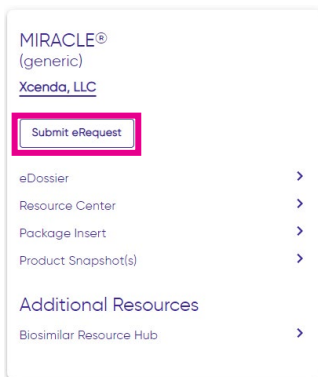


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Request resources from any biopharma company



- The **eRequest** button* allows streamlined requests to be made for eDossiers and other resources
- HCDMs can submit requests to multiple biopharma companies in one place

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eRequest Center - eRequest Tool

The eRequest Tool is designed to help you communicate specific information requests to manufacturers. This tool generates detailed eRequest letter(s) that are submitted to the designated manufacturer(s).

Enter another product name to request

Products being requested:

MIRACLE®

Additional Message to Manufacturer:

Send

Show Important Notes Advanced eRequest Tool

Interact with eDossiers

MIRACLE®
(generic)
Xcenda, LLC

Submit eRequest

eDossier >

Resource Center >

Package Insert >

Product Snapshot(s) >

Additional Resources

Biosimilar Resource Hub >

- **eDossiers** are digitized dossiers in HTML format that allow HCDMs to toggle between sections to access specific information quickly
- Utilize FormularyDecisions proprietary tools to create notes, bookmark sections, and view 2 eDossiers side by side

eDossier | MIRACLE® (generic) ✓ Published and Verified

Page 11 of 55

Master Admin

MIRACLE® (generic)
Xcenda, LLC

Submit eRequest

eDossier >

Resource Center >

Package Insert >

Product Snapshot(s) >

Additional Resources

Biosimilar Resource Hub >

OUTLINE

REVISION HISTORY

TABLE OF CONTENTS

1 EXECUTIVE SUMMARY

2 PRODUCT INFORMATION AND DISEASE DESCRIPTION

3 CLINICAL EVIDENCE

4 ECONOMIC VALUE AND MODELING REPORT

5 ADDITIONAL SUPPORTING EVIDENCE

6 DOSSIER APPENDICES

Miracle Drug for the Treatment of Serious Disease Formulary Submission Dossier

1 EXECUTIVE SUMMARY: CLINICAL AND ECONOMIC VALUE OF MIRACLE DRUG

Serious Disease is a chronic disease that affects more than 8 million American adults (American Association of Serious Disease [AASD], 2015). Serious Disease impacts multiple systems of the body, including the muscular, respiratory, and cardiovascular systems and, if untreated, can eventually lead to complications, including organ failure and death (Smith et al., 2015a). Currently, there is no cure for Serious Disease. Treatments mainly focus on symptom relief during the early stages of the disease and palliative care at later stages.

1.1 Clinical Benefits

Miracle Drug is the first agent in a new class of novel and potent treatments for Serious Disease (Pinto et al., 2016). It is effective against Serious Disease in the early-onset patient population, compared with standard care with Comparator. Clinical evidence supporting the use of Miracle Drug for the treatment of Serious Disease is presented below, with additional details provided in [Section 3](#).

Two identical pivotal phase 3 trials, MIRACLE I and MIRACLE II, enrolled more than 2,000 patients. Both studies compared the safety and efficacy of Miracle Drug and Comparator in adults with early onset of Serious Disease. The primary endpoint was objective response, defined as the percentage of patients not progressing to late-stage disease. Secondary endpoints included survival rate and safety.

In both MIRACLE I and MIRACLE II, Miracle Drug was shown to be more effective than Comparator in patients with Serious Disease, resulting in a higher percentage of patients with objective response (Figure 1).

Access and review additional information in the Resource Center

MIRACLE®
(generic)
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Additional Resources

[Biosimilar Resource Hub](#) >

Biopharma companies can share relevant product information for HCDM review in the **Resource Center**

- Relevant clinical trial data
- Clinical guidelines or pathways
- Real-world evidence
- Economic models
- Other educational information

Resource Center

Prescribing Information
Patient Information
Medication Guide
Instructions For Use

Resource Center

Content in this section curated by manufacturer

MIRACLE® (generic)

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Nulla malesuada pellentesque elit eget. Vitae ultricies leo integer malesuada nunc vel risus commodo viverra. Faucibus ornare suspendisse sed nisi. Urna et pharetra pharetra massa massa ultricies. Varius morbi enim nunc faucibus a. Pretium lectus quam id leo in vitae turpis massa. Quis risus sed vulputate odio ut enim. Consectetur adipiscing elit ut aliquam purus sit amet. Nulla at volutpat diam ut. Libero justo laoreet sit amet. Sit amet nulla facilis morbi tempus iaculis. Sit amet purus gravida quis blandit. Pellentesque diam volutpat commodo sed egestas egestas fringilla phasellus. Sed augue lacus viverra vitae congue eu consequat ac. Tempor id eu nisi nunc mi ipsum faucibus.

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FormularyDecisions Team

Example of a FormularyDecisions healthcare decision maker (HCDM) Newsletter

EXPAND [-]
2/1/2022 1:45:36 PM

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Details
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Preapproval Information Exchange (PIE) Information on Miracle

Preapproval information exchange (PIE) is the communication of clinical and health care economic information (HCEI) on therapies in development between U.S. population health decision makers (PHDMs) and drug manufacturers before regulatory approval.

EXPAND [-]
1/26/2022 4:10:01 PM

Download
View
Edit

Link to emerging evidence on individual Product Pages, Disease State Pages, Therapeutic Area Pages, and Resource Hubs

Metasearch Results

Note: Metasearch results are based on specified criteria; however, control remains with individual sites for the return of relevant information.

Publication	Title	Date
National Institutes of Health	Aspirin: Bitter pill or miracle drug? - PubMed	Aug 11, 2021
National Institutes of Health	Miracle drug, poison, or placebo: patients' experiences with	Jun 19, 2021
ClinicalTrials	The Impact of Social Proximity on Conversion to Generic Prescription Medications	May 17, 2021
ClinicalTrials	The Effect of Providing Free Samples of Generic Cardiovascular Medications to Physicians	May 17, 2021
UpToDate	Kidney transplantation in adults: Overview of care of the adult kidney transplant recipient	May 17, 2021
UpToDate	Antiseizure medications: Mechanism of action, pharmacology, and adverse effects	May 17, 2021
UpToDate	Initial treatment of epilepsy in adults	May 17, 2021
UpToDate	Attention deficit hyperactivity disorder in children and adolescents: Treatment with medications	May 17, 2021
Centers for Disease Control and Prevention	Preventing Chronic Disease Perceptions of and Barriers to Use of Generic Medications in a Rural African American Population, Alabama, 2011 - CDC	May 17, 2021

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Product Pages contain peer-reviewed articles and documents from leading scientific resources using a metasearch engine, including:

- PubMed
- ClinicalTrials.gov
- Pharmacist's Letter
- The Medical Letter
- Medscape
- Food and Drug Administration (FDA)
- UpToDate.com
- Journal of the American Medical Association (JAMA)
- British Medical Journal (BMJ)
- National Institutes of Health (NIH)
- ...and more!

Exclusive offerings and curated resources on FormularyDecisions



"FormularyDecisions is a valuable repository of information related to medications and their clinical utility. It is a central source to obtain the basic clinical information, easily compare medications, and evaluate the economic value based on organizational evaluations, like ICER reports."

— Clinical Pharmacist, Health Plan

Biosimilar Hub

Biosimilar State Substitution Laws

State	Citation Bill Number Lead Sponsor	FDA Must Certify Interchangeability	Prescriber / Doctor "Notification" or "Communication" Required?	Timeframe for "Notification" or "Communication"	Patient Notification Required?	Prescriber's "Brand Medically Necessary" or "Dispense as Written" Blocks Substitution	Pharmacy Records Must Be Retained	Posted List of Interchangeables	Type of Message ("Communication" "Notification")
Alabama	SB 245 Signed 2019 Sponsor: Butler	Yes	Yes	24 hours	Yes	Yes	Yes	Yes	Communication
Alaska	SB 32 Signed 7/13/2018 Sponsor: Sen. Theobald (R-F)	Yes	Yes	3 days	Yes	Yes	Yes	Yes	Communication

Assess biosimilar value with:

- An organized **table of FDA-approved indications** of biosimilars and their innovator products
- The **latest biosimilars market and pipeline landscape information** categorized by development phase, launch status, and interchangeability
- A dynamic repository of **state substitution laws** and biosimilar products, outlining substitution laws in the states that have passed laws that permit or require pharmacists to dispense an interchangeable biological product in certain situations
- **Curated biosimilar resources**, featuring the latest guidance from FDA, 42 ICER reports, relevant articles, and white papers

Cell & Gene Therapy Hub

Cell & Gene Therapy Hub

Landscape Overview Reports & Resources

ICER Reports with Cell & Gene Therapy Hub

Atidarsagene Autotem Cell Therapy
Final Evidence Report

Gene Therapies for Hemophilia A
Final Evidence Report

Gene Therapy for Hemophilia B
Final Evidence Report

Gene Therapy: Under Review
Policy Summit Report

Relevant Resource

CGT Solutions
Cencora | December 2024

Sector Snapshot: Cell & Gene Therapy
ARM | December 2024

Brief: Building Blocks of Cell & Gene Therapy
ARM | November 2024

Gene Cell + RNA Therapies
ASCT | October 2024

A Transformative Therapies
ARM | January 2024

Landscape Overview Reports & Resources

Note: Data maintained by Cencora, Last updated: February 2024

Legend

- AA Accelerated Approval
- BT Breakthrough Therapy
- FT Fast Track
- OD Orphan Drug
- RH Regenerative Medicine Advanced Therapy (RMAT)

Pipeline

- Cell therapy (1)
 - avapocicel (avapocicel)
Pluri Inc. | Phase 2
OD
- Gene therapy (5)
 - Fidanacogene elaparovect (fidanacogene elaparovect)
Pfizer Inc. | Pending
 - SB-525 (groctocogene fleparovect)

Approved

- Gene therapy (1)
 - BMN-270 (valoctocogene rosaparovect)
BioMarin Pharmaceutical Inc. | First approval in 2023

Launched

- Gene therapy (1)
 - AMT-061 (etranacogene dezaparivect)
uniQure Inc. | First approval in 2022
- Gene-modified cell therapy (1)
 - BB-305 (autologous CD34+ cells encoding (A-TPO)-globin gene)
Bluebird Bio | First approval in 2022

Access cell & gene therapy resources on FormularyDecisions:

- Interact with a comprehensive map of the **CGT landscape**, nearly organized by therapeutic area
- Find **pipeline, approved, and launched therapies**, each accompanied by key details like manufacturer, phase, approval year, launch status, and FDA designations
- Dive deeper with **curated publications and reports** from trusted sources like the Alliance for Regenerative Medicine, the American Society of Gene and Cell Therapy, and the FDA

Formulary Coverage Insights and Data

Select Plan Type(s):

All

Overview

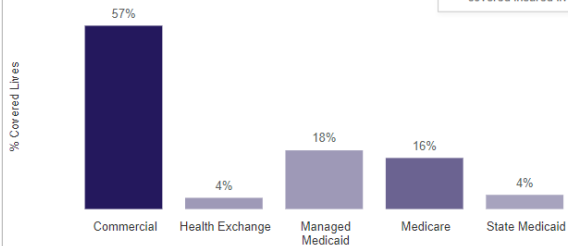
Pharmacy

Medical

Definitions

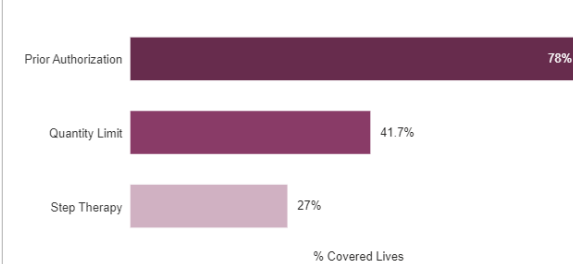
Pharmacy Formulary Coverage by Plan Type

Percent of covered lives listing MIRACLE® with some sort of coverage



All Plans = 7,344
representing 297,071,161
covered insured lives

Percent of Covered Lives with Formulary Restrictions



Selected: All plan types

Pharmacy Formulary Coverage Status

All reported data is based on pharmacy formulary plan coverage
Medical plan coverage data is not represented

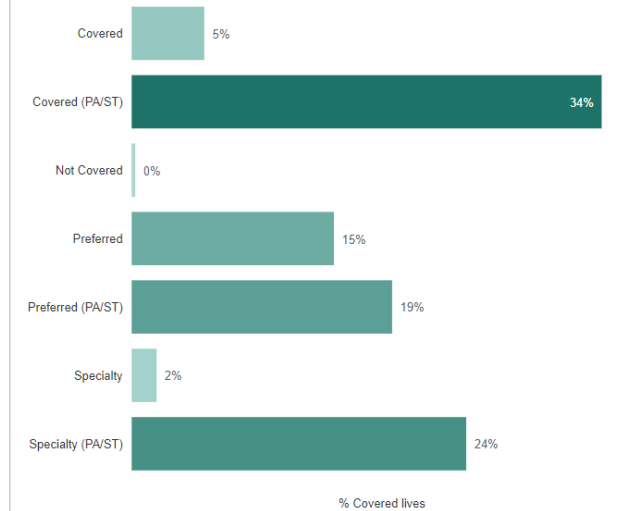
% Plans

% Lives

Drug Tiers

Unlited Tiers

Hover over bars for more details



Data sourced from MMIT (Managed Markets Insight & Technology, LLC.)

Obtain insights on how peer organizations are managing coverage and restriction of products

Find this tool on the Product Page of every FDA-approved product

Data is sourced from MMIT (Managed Markets Insight and Technology)

Product Snapshots

Snapshot

MIRACLE®
(generic)
[Xcenda, LLC](#)

[Submit eRequest](#)

[eDossier](#) >

[Resource Center](#) >


[Package Insert](#) >

[Product Snapshot\(s\)](#) >

[Additional Resources](#)

[Biosimilar Resource Hub](#) >

FormularyDecisions®

 **UMass Chan**
MEDICAL SCHOOL

Commonwealth
Medicine

Product Snapshot

Pipeline

MIRACLE® (miraculate)

Provided to you by FormularyDecisions
Last updated 03/23/2022
Prepared by Pharm A. Cist, PharmD

Curated by clinical pharmacists, **Product Snapshots** are a source of product information to help HCDMs jumpstart the product review process. With a focus on pre-approval products, **Product Snapshots** contain the following pieces of key information:

- Manufacturer
- PDUFA date
- Approved indication(s)
- Therapeutic class
- Mechanism of action
- Dose and administration
- Epidemiology of disease
- Distinguishing factors of product
- Relevant disease background and treatment guidelines
- Key comparators
- Clinical trials overview
- P&T considerations

Product Overview

Manufacturer	Funentech, Inc.
Status	PDUFA date: 05/10/2030
Proposed indication	Miracles in patients with miracle deficiency
Therapeutic class	Miracle receptor agonist (MRA)
Mechanism of action	Pharmacodynamic studies have shown that miraculate selectively binds and agonizes the miracle receptor in the central nervous system (CNS), which activates downstream miracle signaling in patients with miracle deficiency ¹
Formulation	Oral tablet
Dose and administration	<ul style="list-style-type: none"> • Dosing: 300 mg twice daily • Route of administration: oral • Setting of administration: outpatient

Clinical Guideline Snapshots

Curated in collaboration with *The Medical Letter*, **Clinical Guideline Snapshots** provide a summary of key information from published clinical guidelines and highlight the most recent updates for specific disease states.

The screenshot shows a navigation menu on the left with 'Clinical Guideline Snapshots' highlighted. The main content area features the following text:

FormularyDecisions®
The Medical Letter®

Clinical Guideline Snapshot

Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization from Severe Respiratory Syncytial Virus (RSV) Infection During the 2022–2023 RSV Season

Last updated August 26, 2022
American Academy of Pediatrics (AAP)

Provided to you by FormularyDecisions
Last updated November 19, 2022
Prepared by The Medical Letter, Inc.

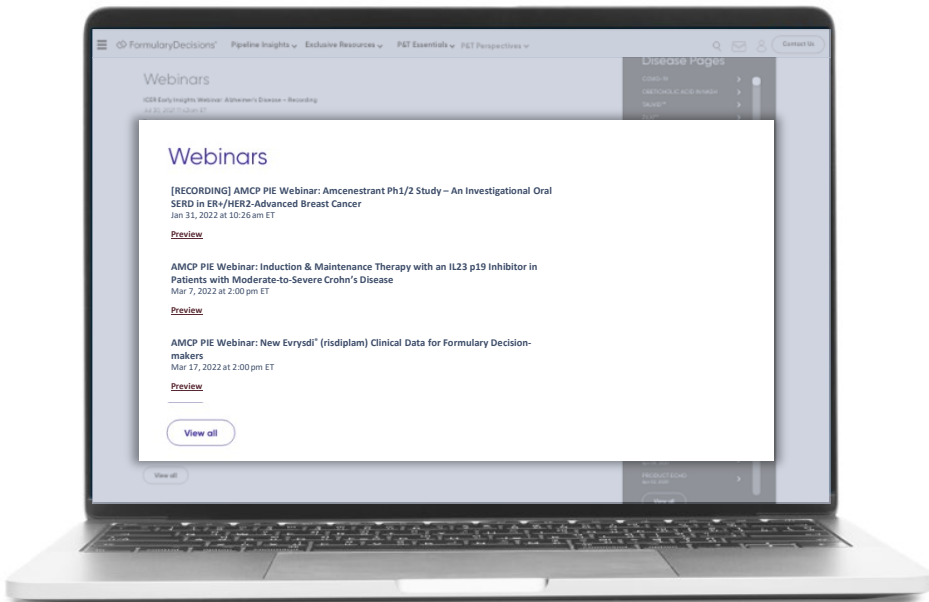
What type of information is provided in the Clinical Guideline Snapshots?

- **Clinical guideline overview**
 - ✓ Date of last guideline publication
 - ✓ Summary of clinical guideline
 - ✓ Changes since the last guideline publication
 - ✓ Epidemiology of relevant disease state
 - ✓ Treatment algorithms
- **Clinical considerations**
 - ✓ Recommendations and strength of recommendations
 - ✓ Recommendations for specific products
 - ✓ Recommendations for specific populations

Clinical Guideline Overview

Date of publication	Current guideline: August 1, 2014¹ ; reaffirmed 2019 Updated guidance: November 17, 2022² ; interim guidance presumed to expire December 31, 2022, unless otherwise specified
Summary	The updated guidance discusses palivizumab prophylaxis to prevent hospitalization for respiratory syncytial virus (RSV) infection during the 2022–2023 RSV season; it is in addition to the current guideline which was published in 2014 ¹
Changes since last guideline publication	<ul style="list-style-type: none"> • Because of a change in the seasonality of RSV due to the COVID-19 pandemic, the AAP supports the use of palivizumab (5 consecutive monthly doses to provide protection for the length of a typical RSV season) in eligible infants in any region experiencing rates of RSV activity at any time in 2022 similar to a typical fall-winter season • The AAP supports providing >5 consecutive doses to eligible children if RSV disease activity persists at high levels (data supporting use beyond 5 months are lacking)

AMCP Pre-approval Information Exchange (PIE) Webinars



AMCP PIE webinars allow HCDMs to:

- Participate in an early, meaningful, and effective exchange of information for preapproval products
- Plan for future drug approvals and reimbursement decisions and forecast future budgets

Register today for your complimentary
Formulary Decisions account at
www.formularydecisions.com/register

U.S. Opioid Settlement Injunctive Relief

July 2022

What is Injunctive Relief?

- In March 2022, AmerisourceBergen, Cardinal and McKesson agreed to a nationwide settlement that resolves most of the thousands of opioid-related lawsuits filed by state and local government entities across the country.
- As part of the agreement, court-ordered injunctive relief will apply to each distributor's Controlled Substance Monitoring Program (CSMP) to ensure consistency across the industry.
- The injunctive relief terms will go into effect on July 1, 2022, and will impact all customer who are registered with the DEA as a retail pharmacy including independents, chains and mail order pharmacies.
- For the latest information and details about injunctive relief, visit: amerisourcebergen.com/injunctiverelief

What's changing?

- AB will be making changes to our **Controlled Substance Monitoring Program (CSMP)**. These changes will ensure consistency in our approach to Controlled Substance distribution across the industry and will impact how we conduct diligence reviews, data collection and analysis, monthly limits on controlled substance ordering, and suspicious order reporting.



A higher quantity of order lines will be flagged – flagged order lines will be automatically cancelled and reported.

- Our new algorithm is designed to automatically flag order lines of unusual size, frequency or pattern
- Order lines that are flagged by the algorithm will be automatically cancelled and reported
- Only the lines of your order that are flagged will be cancelled, the rest will ship.
- If you're routinely having items cancelled and are unable to meet legitimate medical needs of your patients, there's a process to request a threshold review



AB will make unannounced pharmacy visits to observe and speak with the responsible pharmacist.

- Historically, we've notified you in advance if we needed to do an on-site visit for due diligence.
- As part of the settlement agreement, we are required to make unannounced visits.
- These may be performed by our third-party partner, Pharma Compliance Group (PCG) – they will provide identification credentials
- You may contact your AB representative to validate that it is a legitimate visit



We will be required to collect 90 days of de-identified dispensing data from you more frequently

- Please ensure you have processes in place to efficiently turn over this data to AB or our HIPAA-compliant technology vendor, when requested
- If you request a threshold review, you will also be required to submit this information in support of your request.

Current AB POC's

DOD CONTACT LIST

DOD Accounts Receivable	CONTACT NAME	EMAIL	PHONE
	A/R Team	DODAR@amerisourcebergen.com	866-858-0599
	Terry Tyo, Supervisor	ttvo@amerisourcebergen.com	Mon - Fri: 8am -5pm (EST)
	Catalina Montoya	cmontoya@amerisourcebergen.com	
	Ileana Echevarria	iechevarria2@amerisourcebergen.com	
	Sirry Henry	shenry@amerisourcebergen.com	
	Yolaiza Crouch	yolaiza.crouch@amerisourcebergen.com	
Account Services	A/S TEAM	accountservicesCSP@amerisourcebergen.com	844-234-0546
	Jeremy Miller, Manager	jemiller@amerisourcebergen.com	484-644-5198
	Kimberly McClain-Wilkerson	kmcclain-wilkerson@amerisourcebergen.com	630-276-4200 X 1352591
	Maria Barrios	maria_barrios@amerisourcebergen.com	610-727-2265
DOD AXL LIASON		axldod@amerisourcebergen.com	
	Sharon Pritchett (East)	spritchett@amerisourcebergen.com	609-364-3656
	Yessenia Ramirez Robles (West)	yramirez@amerisourcebergen.com	630-200-2570
Customer Systems Support User Services/ Technical Support		customersystemssupport@amerisourcebergen.com	888-711-5469
AB ORDER Account Setup	Deanne Spears, CSS Specialist	dwspears@amerisourcebergen.com	610-727-2463
AB ORDER Account Setup/ Tech Supp		Customersystemssolutionspecialists@amerisourcebergen.com	
DOD Customer Maintenance	Denise Polen	CIDM@Amerisourcebergen.com	614-354-2945
	DOD Customer Maintenance	dpolen@amerisourcebergen.com	
DOD Customer Service	Mon - Fri 7am - 11pm (CST)	DODservice@amerisourcebergen.com	844-222-2273
National Customer Support		DODsupport@amerisourcebergen.com	OR 877-774-6329
			FAX 888-294-0857
OCONUS Customer Service	Mon - Fri 7am - 11pm (CST)	dodoconus@amerisourcebergen.com	855-283-1104
EDI	Rob Such	rsuch@amerisourcebergen.com	847-307-8580
	B2B EDI Data Exchange	edisupport@amerisourcebergen.com	
		DESEDI@amerisourcebergen.com	
ASD Healthcare	Available 24/7	Customer Service	800-746-6273 OR 800-837-5403
			877-639-6390
ASD AFTER HOURS		EMERGENCY, WEEKENDS AND HOLIDAYS	
Sr Director Government Business Development - HS&SS	Alex Merritt	amerritt@amerisourcebergen.com	312-533-8015
Sr Director Government Business Development - HS&SS	Aaron Middlekauf, Pharm.D. CAPT, USPHS (ret)	aaron.middlekauff@amerisourcebergen.com	703-223-4148

PPV Program Overview

- Current Global PPV contract expired Nov 2024 (bridge in place until Nov 2025)
- MTFs worldwide (except Navy's fleet contract & Dakota's)
- Emergency Orders
- Reverse Distribution Program
- DMS back-up PPV supplier
- National Prime Vendor Contract (17 Dec 2022)/ TPharm5 (1 Jan 2023)

Optimizing Stockage of Gov Contract Meds, Solutions

- Government contracts/rebates
- TAA compliance/NAD
- Stock levels

**Supply Chain – not every disruption is caused by regulatory or facility issue
(ie-Triplicatedemic, GLP-1's, ADHD Med Therapy)**

Most GLP-1's

- Obesity vs Diabetes Interplay
- Brand marketing tactics/bait and switch for maintenance tx
- Significant demand/major shortages

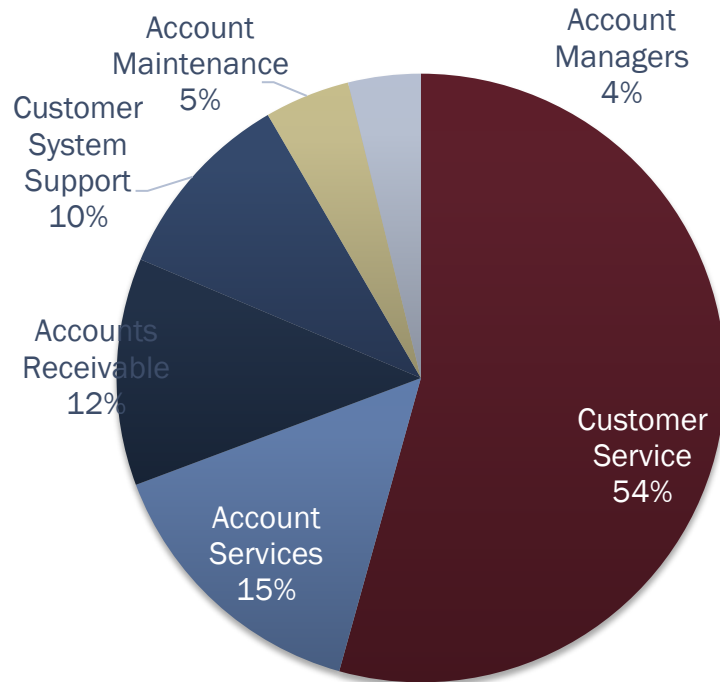
ADHD Meds

- Change in prescribing dynamics
- Increased media attention
- Inc Demand/Significant Shortages
- Inc prescribing/Pandemic/Mental Illness/Telehealth Access

DoD Pharmacy Customer Service Topics

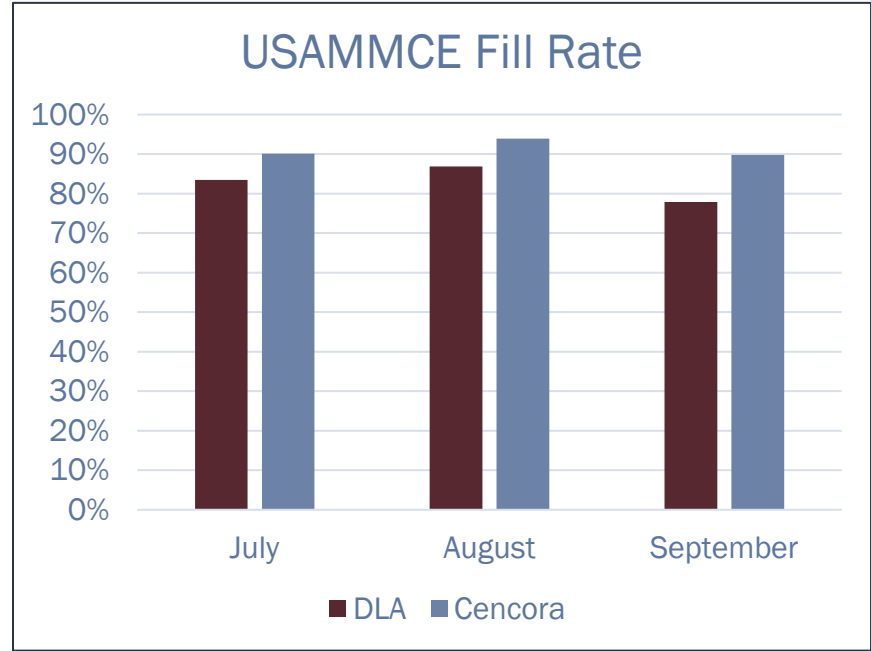
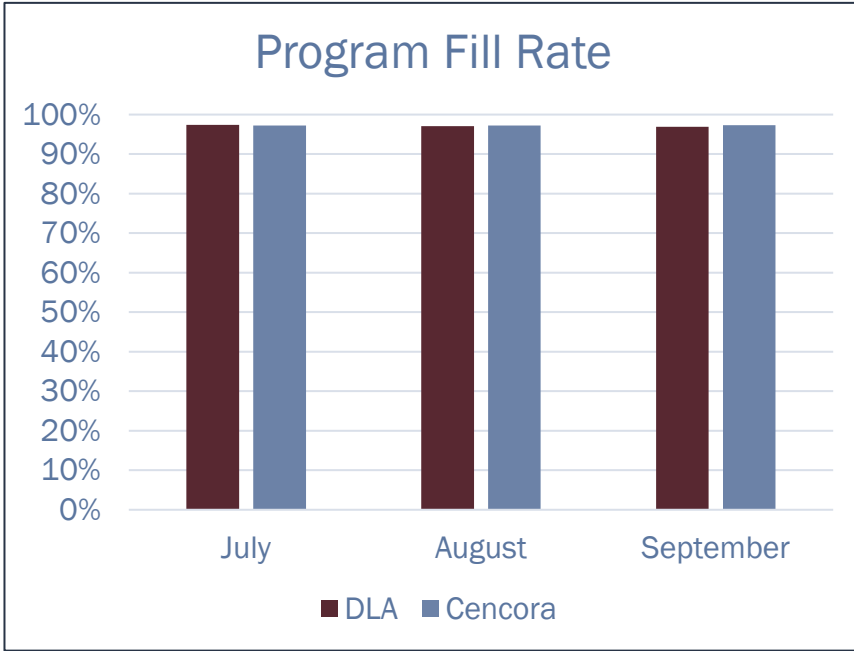
GPV - Over 13K DOD related cases created July- September 2024

Customer Service	<ul style="list-style-type: none">• Returns & Claims• Order Status• Standard Order
Account Services	<ul style="list-style-type: none">• Fail to pick• Purchase History Reports• Delayed Deliveries
Account Management	<ul style="list-style-type: none">• Product Inquiry• Standard Order• Contracts Inquiries
Customer System Support	<ul style="list-style-type: none">• Administrative• Multifactor Authentication• New Account Activation
Account Maintenance	<ul style="list-style-type: none">• Account Setup• Item eligibility Requests• General Account Maintenance
Accounts Receivable	<ul style="list-style-type: none">• AR Inquiry



GPV Fill Rate Review

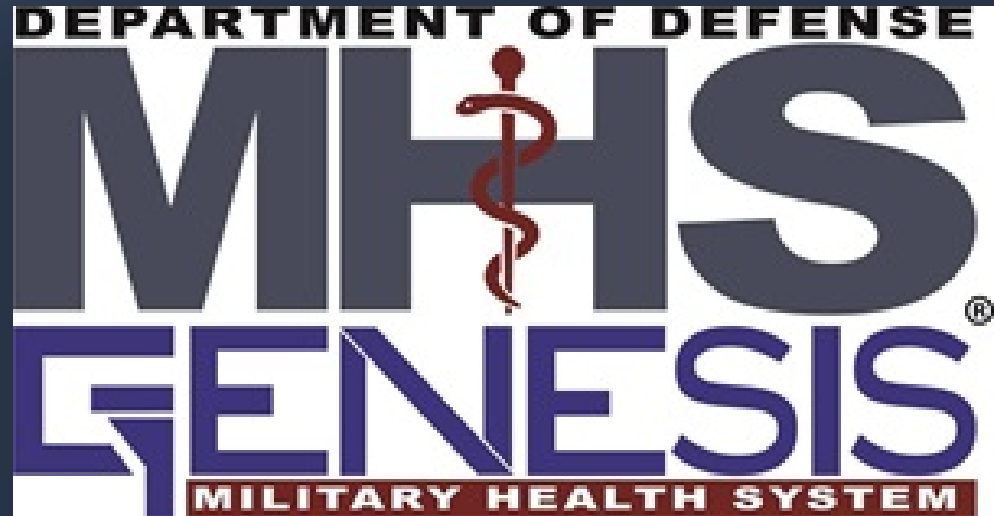
CONFIDENTIAL



PROGRAM	July	August	September
DLA	97.4%	97.1%	96.9%
Cencora	97.2%	97.2%	97.3%

USAMMCE	July	August	September
DLA	83.5%	86.9%	77.9%
Cencora	90.1%	93.9%	89.8%

**ABC Order Integration – inventory, order optimization,
etc.**



Post-Retirement Advice

-TAPS

-Partner with veterans' group

-A lot of changes on the horizon

MTF & DC Visits

PLEASE JOIN US FOR AN
EVENING OF ENTERTAINMENT

ADMIT ONE

DAY	September	Time	VENUE
	18 2023		

Address Line 1
Address Line 2

ADDITIONAL INFORMATION ABOUT THE EVENT

RSVP

by (date)

Hosted by (host's name)

Phone / Other
Email / Other

Self Assessment Questions

- Pharmaceutical Prime
Vendor Program Overview
- Drug Supply Chain,
Optimizing Stockage of Gov
Contract Meds, Solutions
- Remedies to Common
Problems

Self Assessment Questions

- Name the pharmacy contracts AB partners with DoD in delivering:
 - Global Prime Vendor and National Prime Vendor
- List the AB contacts or resources to assist in facilitating supply chain issues experienced by DoD:
 - Government Team – Account Managers, Teresa Oakley, A/R, Contracts, DSCSA
- Identify efficiencies and resources extended as a DoD stakeholder:
 - ABC Order, MedTray, Supply Chain Insight

Enjoy your time in Tokyo!!!



CPE Information

To earn CPE credit, follow the steps below:

- 1) Visit the link below to access the CPE Site for this activity: <https://tinyurl.com/ReadyMedServices>
 - 2) Post-Event Evaluation for this CPE activity using the GREEN registration button (if you have not claimed CE credit through the UT Austin College of Pharmacy CPE site before, you will be prompted to create a CPE profile before you may register for this activity).
 - 3) After you are registered for the activity, submit the green evaluation button that will appear (please note: the evaluation will remain inactive until the last session is scheduled to end).
 - 4) Upon submitting the online evaluation, CPE Credit will automatically upload to your NABP CPE Monitor profile (allow 2-3 days).
 - 5) **Evaluations must be completed before June 20, 2023 or you forfeit CPE credit.**
 - 6) **IMPORTANT NOTE:** It is the participant's responsibility to check their online CPE Monitor Profile to confirm CPE credit is accurately reflected or contact UT Continuing Pharmacy Education before August 5, 2021 to resolve any discrepancies. CPE credit cannot be awarded or corrected after
- 5.



The University of Texas at Austin College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.



Attendance Code



<https://tinyurl.com/ReadyMedServices>



Questions?



Improving Health and Building Readiness. Anytime, Anywhere — Always

