

NHIA TALK INFUSION WEBINAR

2021 Policy Update and NHIA's Efforts to Promote Equitable Access for Home Infusion Services

February 24, 2021

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Today's Speakers



Connie Sullivan,
BSP Pharm
President & CEO



Bill Noyes,
**Senior Vice President of
Reimbursement Policy**



Shea McCarthy,
**Director of
Legislative Affairs**

Agenda



2021 Policy Priorities



Advocacy & Data



2021 Legislative and
Regulatory Landscape



Reimbursement

2020 Accomplishments

Retirement of the Medicare Part B PN and EN LCDs

Termination of the FDA Unapproved Drugs Initiative*

Submitted 10 comment [letters](#) to HHS/CMS/FDA

Legislation introduced in House and Senate to fix definition of “home infusion calendar day”

Publication of Infusion Industry Trends 2020

Launched the NHIA [Fellow Program](#)

New and improved [NHIA website](#)

Updated the member database platform

Offered 31 hours of [continuing education](#) programming

NHIF Published first industry-wide benchmarks for [Home Infusion Patient Satisfaction](#)



2021 Policy Priorities



Medicare Part B



Part D Home
Infusion
Demonstration



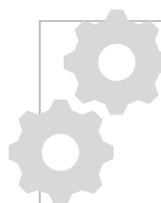
COVID-19
Treatments and
Vaccines



DMEPOS Rule



FDA MOU
Implementation

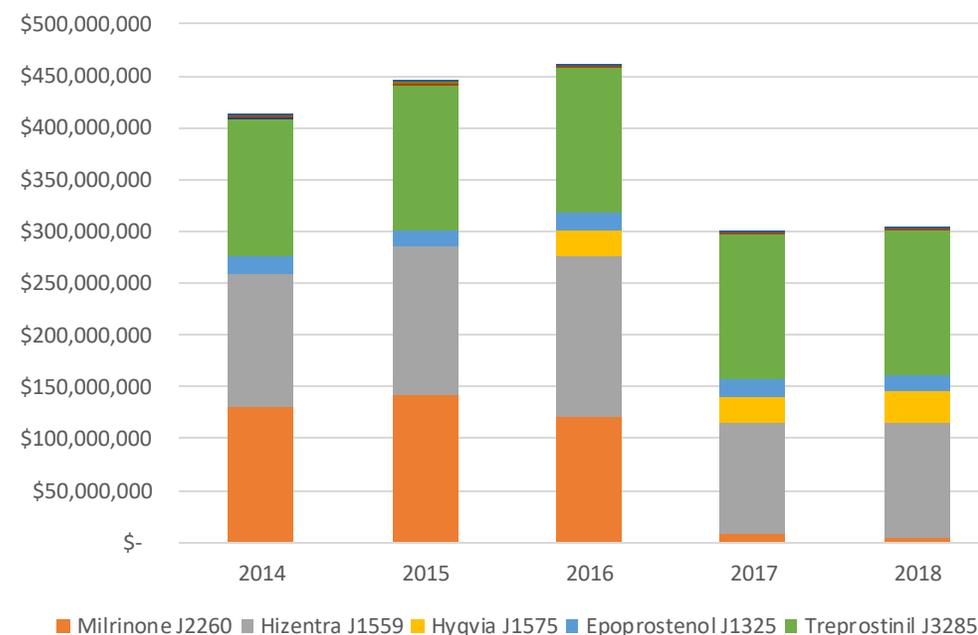


UDI Initiative

Medicare Part B

- Re-introduce legislation requiring CMS to:
 - Pay home infusion therapy suppliers each day of administration
 - Recognition of pharmacy professional services
 - Fix the home health intersection
- Share data with CMS and legislators regarding declining utilization, cost and services

Annual Spend for DMEPOS Drugs 2014-2018



Part D Home Infusion Demonstration

Eligible Providers

- Pharmacy enrolled in AB MAC
- HIT Services supplier + license to dispense medication (Rx or MD)

Drugs

- Drugs billed to Part D
- Scope TBD
- Requires IV administration (no 15 min. rule)

Services and Supplies

- Pharmacy and nursing services, supplies
- Bundled payment billed to AB MAC
- Paid every day of infusion
- No physical presence requirement
- Intersection with home health

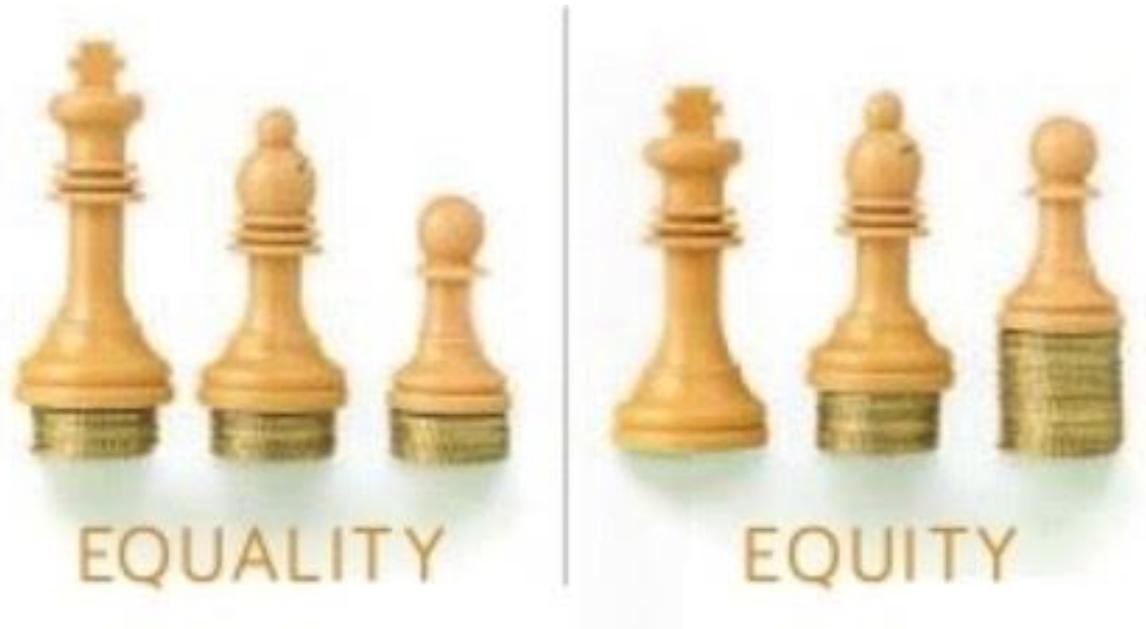
COVID-19 Treatments & Vaccines

Treatments

- Increase reimbursement for home administration of COVID-19 monoclonal antibodies
- Direct access to product for home infusion use

Vaccines

- Make pharmacy services billable separate from administration
- Direct access to vaccines



DMEPOS Rule

- Published November 4, 2020
- Reclassifies when an item of DME is appropriate for use at home
- Would potentially expand coverage to healthcare professional-administered drugs when:
 1. The FDA labeling requires the home infusion drug to be prepared immediately prior to administration, or administered by a health care professional or both; and
 2. A qualified home infusion therapy supplier administers the drug or biological in a safe and effective manner in the patient's home; and
 3. the FDA labeling specifies infusion using an external infusion pump as a possible route of administration, at least once per month, for the drug.



FDA Compounding MOU

- Finalized October 26, 2020
- Provides state Boards of Pharmacy 365 days to decide whether to sign the MOU
- Requires pharmacies that dispense “inordinate amounts” of compounded drugs interstate to submit data for reporting to FDA
- NHIA sent a letter to FDA and NABP with recommendations for improving implementation to avoid disruption of care

Unapproved Drug Initiative

- On November 25, 2020, HHS issues a terminated the Food and Drug Administration's Unapproved Drugs Initiative
- UDI was launched through a guidance document that was issued in 2006 and updated in 2011, without notice and comment rulemaking
- The program's objective was to reduce the number of unapproved drugs on the market. Offered de facto market exclusivity
- UDI had the unintended consequence of markedly increasing the cost of the drugs subject to the program without providing a corresponding benefit
- This action is currently being reviewed by the Biden administration and could be reversed



2021 Legislative and Regulatory Landscape

Democrats Gain Control of Washington

- The Biden administration is already taking major steps to unwind the Trump administration's health care agenda.
 - E.g., ACA marketplaces, Medicaid work requirements
- With a bare Senate majority including Vice President Kamala Harris' vote, Democrats will spend much of 2020 attempting to move legislation without Republican support.
- While **budget reconciliation** has procedural limitations, it allows the Senate to move major legislation with only 50 votes instead of the 60 that are typically needed to avoid a filibuster.

Biden's \$1.9T COVID Relief Package

- The House is expected to pass President Biden's \$1.9 trillion COVID relief package later this week or over the weekend.
- Senate Democrats have been trying to “pre-conference” the bill, although changes in the upper chamber are possible.
- Senate floor consideration could take up to two-weeks, pushing lawmakers to the March 14 deadline when enhanced UI benefits expire.

The ‘American Rescue Plan’

- \$1,400 in direct assistance to individuals, expanded Unemployment Insurance, new employer leave policies, and more.
- \$415 billion to establish a national vaccination program, increase reimbursement for vaccines, expand testing and invest in domestic manufacturing of PPE and other medical supplies.
- Aid to small businesses and local, state and tribal governments.
- Cybersecurity measures.

A Second Reconciliation Package?

- Infrastructure spending is expected to drive the year's second reconciliation package, which Democrats can advance after passing an FY22 budget resolution.
 - While infrastructure will be at the core of the second package, policies impacting health care, tax, and other areas are expected to be included.
- The second budget resolution could advance as soon as late March, and committees are already preparing legislation for inclusion in the next package.
- The process for the second package is likely to be more deliberate, as the Senate is likely to be more engaged now that they have established an organizing resolution and by then will have cleared most of President Biden's cabinet-level nominations.

Regulatory Focus

- As key officials are yet to be confirmed, the Biden administration is focused on reversing many Trump-era policies.
 - DMEPOS rule?
- COVID relief efforts are expected to occupy considerable bandwidth among HHS political appointees for the next several months.
- Ultimately, CMMI could be leveraged to pilot home infusion demonstration programs that expand coverage and access.
- New leadership on the Administration's COVID Response Team has expressed increased appreciation for the value of home infusion.

Data & Advocacy

Cost Data

Utilization
Data

Process
Data

Clinical
Data

2021 Cost Data Initiatives

- Home administration of bamlanivimab white paper

[Open Access Report: A Home Infusion Program for Administration of Bamlanivimab in High-Risk Settings](#)

Table. 3 Summary of costs for providing bamlanivimab at home

Service or Product Description	Cost (Range)
Onboarding	\$108 - \$420
Other Pharmacy Services (i.e., dispensing, billing)	\$75 - \$300
Direct Costs (i.e., administration supplies, PPE, anaphylaxis kits, delivery)	\$70 - \$313
Nursing	\$180 - \$560
General Administration (35%)	\$151
Total	\$584 - \$1,746

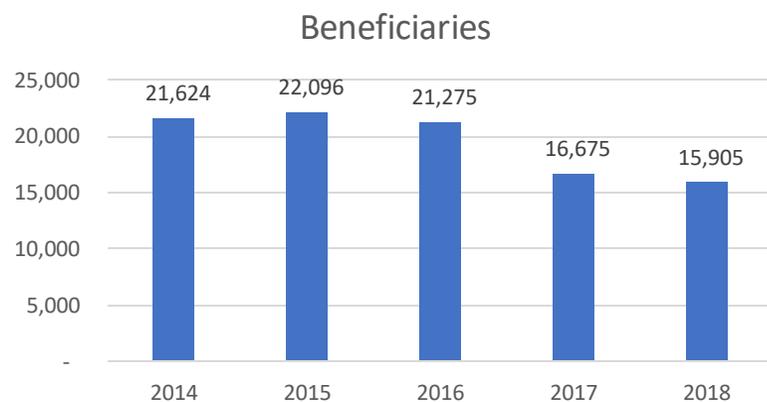
*Amount paid by Medicare - \$309

- Part B Reimbursement
 - Demonstrate non-viability of Cures implementation
- Parenteral Nutrition Cost Initiative
 - Partnership with  WellSky
 - Calculates annual average cost per bag of PN
 - White paper for providers to use in commercial payer contracting

Utilization Data

- Part B DMEPOS
 - Trends in beneficiaries
 - Trends in supplier participation

PlayMakerHEALTH
The Post-Acute Growth Platform



- COVID-19 Treatments

- Rural areas study 



Process Data – Pharmacist Services

Professional Services Study

- Describes and quantifies time spent on common activities performed by home infusion pharmacists
- Correlated with therapy categories

Task Categories

- Assessments
- Care Planning
- Monitoring
- Dispensing
- Care coordination
- Other

Reporting

- Mean time spent per task
- Mean time spent onboarding/ ongoing mgmt.
- % dispensing vs. total time
- % contact days vs. study days
- Mean # tasks per dispense cycle

Clinical Data – NHIF Benchmarking

Status at Discharge – Core Metric

% Therapy Completed

- Antimicrobials
- Chemotherapy
- Other (non-biologic)

% ADR as Reason for DC - all therapies

% Unplanned Hospitalizations as Reason for DC – all therapies

Patient Satisfaction

Composite Scores:
Equipment & Supplies
Communication
Courtesy
Helpfulness
Instruction
Overall Satisfaction
Would Recommend

30-day Hospital Re-admission

All-cause and infusion related 30-day readmission rates

- Parenteral Nutrition
- Inotropes

- Improves quality and efficiency by providing an external comparator
- Dispel myths about home infusion
- Establish safety
- Validates effectiveness of current practices



Data Program Participation Information

Email: NHIFdata@nhia.org



Ryan Garst, PharmD
Sr. Director of Clinical Services

Reimbursement Updates

- 2021 HIT Services
- IVIG Demonstration
- EIP Proposed LCD
- Parenteral and Enteral Nutrition
- Billing of COVID-19 Treatments
- INFUSION Magazine

Home Infusion Therapy (HIT) Services

- Must be enrolled with the A/B MAC as Home Infusion Therapy Service provider.
- Enroll with MAC based on physical location of the pharmacy.
- Limited to a subset of DME infused drugs covered in the EIP LCD.
- Home Health care continue to provide nursing for ALL infused drug therapies that the HIT Services does not apply, such as Part D antibiotics and PN.

NHIA tool https://www.nhia.org/wp-content/uploads/2020/03/Part-B-Tool_v21-1.pdf

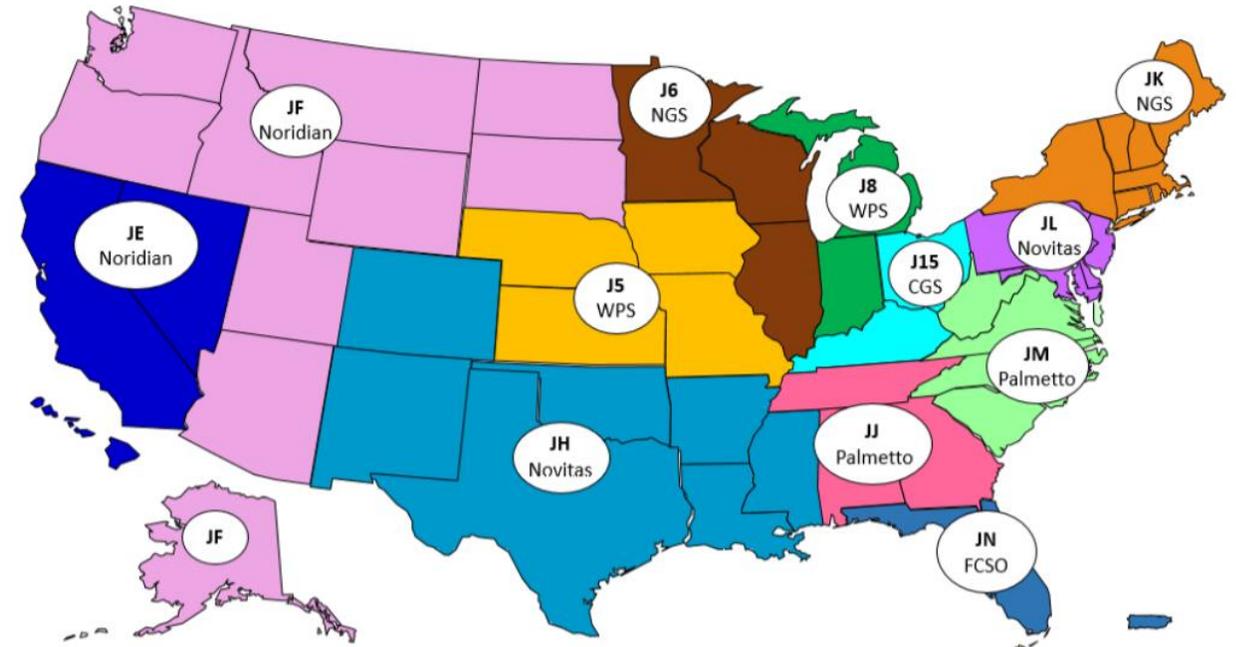


Home Infusion Therapy Services

Rates

HCPCS	Descriptor	Rate
G0068	Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 160.18
G0069	Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 216.43
G0070	Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 269.25
G0088	Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 194.81
G0089	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 263.21
G0090	Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes	\$ 327.46

A/B MAC Map



Link: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview>

IVIG Demonstration

- Extended through 2023
- 2021 allowable for Q2052 is \$381.57

<https://med.noridianmedicare.com/web/ivig/provider-supplier>

Proposed External Infusion Pump LCD

- Would add coverage of SC Hizentra® for CIDP
- NHIA Provided public (verbal) comments and written comments

Parenteral and Enteral Nutrition LCD were retired in Nov. 2020

- Talk Infusion webinar on Oct. 27, 2020, NHIA and ASPEN
- Published a FAQ based on the many question posed on the webinar.

<https://www.nhia.org/wp-content/uploads/2020/03/Parenteral-and-Enteral-Nutrition-FAQs-V2.pdf>

COVID-19 Treatments Reimbursement

- Must be enrolled to bill the A/B MAC, Pharmacy or Mass Immunizer
- Do not include HCPCS code for drug or biologic on claims when it's provided for free.
- Medicare allowable for mAb administration is \$309.60.
- No patient co-pay or deductible.
- Administration is inclusive of supplies/equipment and services.
- Administration is billed by the entity that administers the product.
- Bill Medicare Advantage to A/B MAC
- Mass Immunizers to use Place of Service (POS) 60

NHIA tool https://www.nhia.org/wp-content/uploads/2020/03/BAM-Pilot_Coding-Billing_v4.pdf

CMS COVID-19 Treatment Resources

- CMS mAb Instructions <https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf>
- CMS Enrollment <https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots>
- CMS HCPCS codes and rates <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>
- CMS FAQ (new) <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf> See BB. Drugs and Vaccines Under Part B – starts on page 120

Claims Processing Issue

- NHIA heard from multiple providers, in different Jurisdictions, regarding claim denials for BAM administration (M0239)
- NHIA reached out CMS with examples asking for direction to resolve with MACs.
- Response 2/18/2021: We are aware of the situation and are working on a fix to address this as soon as possible. The providers will not have to resubmit their claims as the MAC will perform mass adjustments accordingly. I don't know timing on when the adjustments will be made but this is a top priority.



Home Infusion Revenue Cycller

New regular feature in INFUSION Magazine



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