Summary of the Home Infusion Technical Expert Panel Meeting and Recommendations

October 10, 2018

Prepared for:
Centers for Medicare & Medicaid Services
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Introduction

The Centers for Medicare & Medicaid Services (CMS) contracted with Abt Associates (Abt) to support development of a Medicare benefit for home infusion therapy. As part of this contract, Abt convened a Technical Expert Panel (TEP) to obtain input from experts in the field to support the development of a Medicare home infusion benefit. The TEP participated in an introductory webinar on July 26, 2018 and an in-person meeting on August 8, 2018. The purpose of the pre-TEP webinar was to provide background on the current Medicare Fee-for-Service (FFS) coverage of infusion therapy, as well as a summary of the 21st Century Cures Act. The in-person TEP meeting was designed to inform rulemaking for the home infusion benefit legislated in the 21st Century Cures Act; this report summarizes the input that was received from the in-person TEP meeting.

Panel overview

Purpose

The purpose of the in-person TEP meeting was to gather perspectives from clinicians and researchers with experience in home infusion therapy to identify and prioritize recommendations to CMS regarding the development and implementation of a Medicare home infusion benefit, as described in the 21st Century Cures Act.

Structure

The in-person TEP meeting started with a brief overview of the project and discussion of how Abt would be utilizing the TEP to gather feedback on the development of a new Medicare home infusion benefit. Additionally, Abt set expectations for the August 8th meeting and noted that CMS staff would not be participating in the meeting, but would be observing the meeting. TEP members were provided an agenda, participant list, and presentation slides at the meeting. These materials are included in Appendix A.

The TEP meeting covered the following topics:

- Understanding who uses home infusion therapy
- Current trends in home infusion therapy from 2012-2017
- Drugs covered under the Medicare home infusion benefit
- Role of home infusion suppliers
- Payment for Medicare home infusion services
- Non-FFS Medicare infusion coverage/prior authorization

For each topic, Abt Associates led a discussion and sought feedback and recommendations from the TEP members.

Members

The TEP was composed of clinicians, industry representatives and patient representatives. When convening the TEP, Abt reached out to many different groups to solicit representatives for the panel. Relevant groups were asked to nominate one participant with clinical and health management experience. Ultimately, we deferred to each organization to nominate the participant they wished to represent their respective group/association. Panelists who participated in the meeting and the organizations they represent are as follows:

- William Bolgar, PharmD, CVS Caremark/Coram Healthcare
- Paul Celano, MD, Greater Baltimore Medical Center
- Logan Davis, PharmD, National Home Infusion Association
- Lisa Gorski, RN, Wheaton Franciscan Home Health & Hospice
- Alan Koterba, MD, PhD, Allergy Associates of Palm Beach
- Rose Madden-Baer, DNP, Visiting Nurse Service of New York

- Kim Neuman, MA, Medicare Payment Advisory Commission (MedPAC)
- Mitch Patel, PharmD, Cigna Healthspring
- Lynne Warner Stevenson, MD, Vanderbilt University Medical Center
- Kendall Van Pool, National Home Infusion Association

Randy Falkenrath from Humana was also invited to attend but was unable to attend because of last-minute travel complications.

Understanding who uses home infusion therapy

Topics Addressed

Abt presented data on the demographics of home infusion therapy users and solicited feedback on what these data showed about clinical reasons for home infusion. Additionally, Abt asked the TEP to provide feedback on what types of patients they envision might switch to home infusion therapy after a Medicare benefit is created.

Questions

The following questions were posed to the TEP members for discussion:

- What factors are important when referring a patient to home infusion therapy?
- How much switching to home infusion therapy is anticipated?
- Who will switch to home infusion therapy?

Discussion

Major issues raised were as follows:

- **Patient demographics:**
  In terms of understanding differences in home infusion utilization rates by age group, the TEP noted that it was important to consider mortality rate differences for different types of infusion patients. For example, Category 1 may have a higher percentage of under-65 patients because they tend to die young—many patients start receiving these drugs at end of life. This is in contrast to the Category 2 drugs, which tend to be for more chronic conditions. Our analyses showed that life expectancy was much shorter for the Category 1 patients.

  TEP members expressed several hypotheses for the lower utilization rates observed in rural areas. This could reflect access issues, with infusion services not available in some rural areas. It may also be that some patients with chronic conditions relocate to urban areas where access to health care services is better. It may also be that the changes to the drug pricing methodology that went into effect in 2017 had a disproportionate impact on rural providers, who tend to be smaller than their urban counterparts. Differences in utilization rates across geographic regions could reflect differences in practice patterns.

- **Predicting patients switching to home infusion:**
  TEP members said that it would be difficult to predict how many patient will receive home infusion primarily because the decision to switch to home infusion is dependent

on individual patient preferences. In addition, there are other factors outside of the 21st Century Cures Act that are affecting home infusion utilization such as changes in practice patterns. For inotropic patients, TEP members felt it would be difficult to predict changes without knowing what the payment rates and covered services would be since these would impact access to care. But, because the home infusion benefit being developed for the Cures Act is partly a response to the change in drug reimbursement, some TEP members felt like the impact would be small. The Cures Act would help to maintain the number of infusion patients, preventing the substantial decrease that may have occurred in the absence of the legislation. If the Cures Act also covered Part D drugs, the utilization impacts would be much larger. The TEP noted that some patients are reluctant to switch to the home setting, which is a major factor limiting the impact of the Cures Act. TEP members noted that some of the beneficiaries in the IVIG Demonstration may switch to home infusion, as that Demonstration will be ending in 2020

- **Burden on providers:**
  The TEP noted that the Cures Act has a lengthy section on accreditation. One of the TEP members noted that accreditation needs to be robust for both the nursing and the pharmacy components due to safety and quality of care concerns. The TEP also expressed concerns about the burden of the cost of and complying with accreditation standards for home infusion that go above and beyond standards for home health agencies.

  TEP members also emphasized compounding medication in a sterile environment as a significant burden on agencies being able to carry out home infusion. There was disagreement as to whether the requirement that drugs be compounded in a sterile environment is included in Medicare Parts B and D drug reimbursement rates or not. Some TEP members felt that this was implicitly covered in the Medicare reimbursement rates while others felt that it was not.

- **Concern about unintended consequences:**
  We discussed the relationship between the home infusion and Medicare DME benefits. There are only a limited number of home infusion drugs that are covered through the DME benefit. The TEP expressed concerns about potential unintended consequences that could result from some of the provisions of the home infusion benefit. For example the fact that a pump is required in order for a patient to qualify for the home infusion benefit may impact physician prescribing patterns, as an HHA may make the case that the pump is needed. The benefit could encourage needless usage of DME pumps to deliver medication and development of drug delivery methods that would qualify for the home infusion benefit. TEP members expressed

concern about the exclusion of Part D drugs in the home infusion benefit, although they recognized that this was beyond the scope of the TEP meeting.

- **MCG Health Guidelines:**
  None of the TEP members seemed to use the MCG Health Guidelines, and they indicated that they had not seen them before. They did say, however, that the guidelines, for the most part, seem to include the right types of questions.

  In terms of factors that should be considered in deciding whether a patient is appropriate for home infusion therapy, the TEP noted that medical appropriateness is the most important factor. They discussed the importance of the patient's support system and home environment, as well as the role that family and patient preferences have in determining the most appropriate infusion setting. But patient preferences ultimately play a major role in determining whether a patient receives infusion at home versus some other setting. There are lots of patients who would prefer to receive infusion at home but have not been given that option. The TEP also discussed the importance of having qualified, competent staff.

  The TEP discussed the important role that caregiver abilities have in determining whether infusion is successful, although they also noted that some patients do not have a caregiver. Caregiver assessment and training are important for home infusion patients. Caregivers needed to understand the amount of work that will be required and how important it is to be compliant with drug administration procedures. The TEP discussed how difficult it is to know in advance who will and will not make a good caregiver. They noted that social workers can be a valuable resource.

Trends in home infusion therapy 2012-2017

Topics Addressed

The TEP discussed analyses of recent patterns in home infusion utilization and drug spending as well as predict how utilization and drug spending might change in response to the implementation of the 21st Century Cures Act.

Questions

The following questions were posed to the TEP members for discussion:

- How are these patterns expected to change in the coming years, especially after the implementation of the 21st Century Cures Act?
- What drug approvals, clinical practice guideline changes, and other similar changes are expected in the coming years?

Discussion

Major themes that were discussed by TEP members during this session were as follows:

- **Oncology drug utilization:**
  We found a large reduction in utilization of oncology drugs in the home setting. TEP members said that this was likely due to decreases in utilization of Fluorouracil, which occurred after DME MAC clarification and an MLN article on the drug largely highlighted that a DME supplier cannot bill for Fluorouracil if the drug if the treatment began in the physician's office. Although not specific to Fluorouracil, this clarification affected DME claims for the drug disproportionately because it is common practice for physicians to begin a treatment of Fluorouracil in the office and to send them home to continue treatment. Prior to the clarification, there was a high frequency of DME suppliers who would bill for the drug while also billing for delivery of the supplies and equipment after the physician had already billed for the drug. The clarification was designed to avoid double billing for the drug. In addition, an oral form of Fluorouracil has been developed, which has and will continue to decrease IV Fluorouracil utilization.

- **Drug Spending for Home Infusion Therapy:**
  Spending on Category 1 drugs fell dramatically in 2017. TEP members said this was caused by the re-pricing of Milrinone from AWP to ASP + 6% in January 2017. This change resulted in a drastic drop in price for Milrinone and accounts for almost all of the decrease in spending.

- **Immune globulin trends:**

TEP members noted that they are seeing increased use of immunotherapy recently. Two reasons were suggested. One is that the prevalence of immunologists and immune deficiency as a diagnosis has increased over time, and the other is that there are more secondary antibody deficiency patients, possibly caused by the increase in utilization of targeted therapies.

Drugs covered under Medicare home infusion benefit

Topics Addressed

Abt presented the list of covered drugs that qualify for coverage under the 21st Century Cures Act and reviewed the drugs covered under the Bipartisan Budget Act of 2018. The TEP members discussed which drugs should be covered under the 21st Century Cures Act.

Questions

The following questions were posed to the TEP members for discussion:

- Are there any additional drugs that meet the 21st Century Cures Act criteria but are not listed under the Bipartisan Budget Act of 2018?
- Do the three categories make sense clinically?

Discussion

Major issues raised by TEP members during this session were as follows:

- **Covered drugs list:**
  TEP members said some of the drugs listed in the Bipartisan Budget Act of 2018 are no longer used. While some TEP members stated that they did not see any gaps in the list of covered drugs, others recommended exploring the addition of biologics to the list of covered drugs. If the Cures Act were expanded to Part D, then there would be additional drugs that could be covered. The TEP also discussed the self-administered drug exclusion lists, which contain some biologics that patients can be trained to self-infuse. They are not covered by Part B and not part of the Cures Act.

- **Classification of drug categories:**
  The TEP discussed the drug categories used in the Bipartisan Budget Act of 2018 as a potential model for the Cures Act. TEP members noted that the category 1 drugs are more clinically complex than category 2. Several TEP members stated that the classification under the Bipartisan Budget Act of 2018 does not make sense clinically and that it would be better to classify drugs on clinical complexity associated with the drug rather than general drug categories. One example given is that the services required for Fluorouracil treatment are similar to those required for inotropic drugs but the drugs are in different categories. The TEP also noted that utilization of category 3 drugs is very low.

Role of home infusion suppliers

Topics Addressed

The TEP discussed the role of nurses in home infusion using the MCG Health Home infusion Therapy Guidelines as a starting point. Follow-up discussion focused on the level of support necessary for patients and remote monitoring.

Questions

The following questions were posed to the TEP members for discussion:

- Is the list of roles for home infusion nurses complete?
- How much time does it take to complete nurse responsibilities?
- How long does it take to train and educate patients about the provision of infusion drugs?
- How is remote monitoring typically used? Most frequently used types?

Discussion

Major themes that were discussed by TEP members during this section were as follows:

- **Accreditation:**
  TEP members noted that neither DME nor pharmacy accreditation covers various competencies specific to home infusion services. Home infusion accreditation requirements were discussed as well. A key question is what should be part of the accreditation for DME suppliers vs. home infusion suppliers. A key component that is not part of DME is pharmacy. The TEP felt that pharmacy accreditation of infusion suppliers was essential, given that they are supplying drugs to patients. Standards for sterile compounding are needed.

- **Role of nurses:**
  Several TEP members categorized nurse roles into those that occur in the patient's home and those that occur outside of the home such as coordination with other providers. Communication between providers was emphasized as particularly important. TEP members said that home infusion nurses and pharmacies have more responsibilities than providers in non-home settings, such as outpatient clinics. They noted that, while all of the nurse roles that were on the list that Abt presented could be performed by nurses, some of the tasks are often provided by pharmacists. For example, pharmacists sometimes arrange referrals, communicate with team members, and make sure that labelling is clear and accurate. The TEP also noted several activities related to the initial home visit and coordination with other providers that were not included on the list. They also noted that some of the activities on the list

occur when the nurse is outside the home. The TEP also discussed the professional services provided by pharmacists, dieticians, and social workers.

- **Level of support for patients:**
  TEP members noted that patient training and education length of time and level of support necessary depends on the patient. Some patients want to become independent quickly while others are less willing or have less confidence. Some patients require more in-person follow-up visits while others require more telephone follow-up. The type of drug is one factor in the amount of support that patients need, as some types of drugs are more complex to administer, but other factors such as the home environment, the caregiver, the patient's ability to self-infuse, and the patient's motivation are more important. One TEP member noted that certain drugs have much different training requirements because of the complexity of the drug. The TEP notes that training needs to be ongoing and not all by phone, although there is increasing use of video assisted monitoring.

- **Remote monitoring:**
  While some TEP members use remote monitoring for their patients, remote monitoring is not widely used except for telephone follow-up. This is due more to technological limitations than because remote monitoring is not useful. They noted that the technology for remote monitoring is evolving rapidly, and the home infusion benefit should be flexible enough to accommodate and facilitate future changes that allow more care to be provided remotely. The remote monitoring that seems to be most promising is pump-integrated technology to monitor frequency and duration of drug administration.

Payment for Medicare home infusion services

Topics Addressed

Abt reviewed how home infusion services will be paid under the 21st Century Cures Act, including the three factors that the Act says may be considered in developing the payment system (costs of furnishing infusion therapy in the home, payment amounts for similar items and services under Medicare, and Medicare Advantage payment amounts). Abt opened up discussion to solicit feedback on details of payment that have not been explicitly determined by the law.

Questions

The following questions were posed to the TEP members for discussion:

- Are there sources of information on costs of providing home infusion therapy or other sources that CMS should consider as it develops payment rates?
- Do the three payment categories used under the Bipartisan Budget Act of 2018 adequately reflect the therapy type and complexity of the drug administration?
- What other methods should CMS consider to account for patient acuity and complexity of administration?

Discussion

Major themes that were discussed by TEP members during this section were as follows:

- **Payment Adjustments:**
  The TEP members suggested several possible payment adjustments including ones for dexterity, neurologic, and rheumatologic issues as well as adjustments for homebound patients, caregiver situation, and psychiatrically home bound patients. TEP members agreed, however, that there were not currently data available for measuring these patient characteristics, and that the acuity adjustment for payment rates would most likely need to be based on the complexity of drug administration.

- **Payment Categories:**
  TEP members noted that the private sector payment rates are defined much more specifically than 3 broad categories used in the Bipartisan Budget Act of 2018. For the 21st Century Cures Act, it might be possible to have a better payment system than what is specified for the Bipartisan Budget Act of 2018. They noted that CMS should review the drug categories and consider refinements for the 21st Century Cures Act.

- **Payment in private industry:**
  TEP members said that private payers do not adjust specifically for patient acuity because the different rates paid by therapy type and frequency of treatment cover acuity differences.

- **Out of pocket expenses:**
  TEP members expressed concerns about the co-insurance for homebound home infusion patients as they move off of the home health benefit and onto the home infusion benefit, which is covered by Medicare Part B.

- **Outlier Payments:**
  TEP participants noted that outlier payments would likely be dependent on the payment structure. Members suggested that the number of nursing visits and/or complexity of the drug itself, would be the most likely factors in determining an outlier payment.

Non-FFS Medicare infusion coverage/prior authorization

Topics Addressed

Abt showed the TEP members commercial payer data and asked TEP members to discuss the home infusion therapy landscape in Medicare Advantage and the private sector as well as the possibility of prior authorization usage in the Medicare home infusion benefit.

Questions

The following questions were posed to TEP members:

- Are there differences in home infusion users by type of payer?
- Are there differences in home infusion users by type of patient?
- What are the tradeoffs associated with a prior authorization requirement?
- Could a prior authorization requirement be effective in ensuring safe and appropriate utilization?

Discussion

Major issues that were raised by TEP members during this section were as follows:

- **Gender differences:**
  One TEP member noted that chronic disease patients tend to be female, which explains why Category 2, with more long-term users, has a higher percentage of female patient than other categories.

- **Medicare Advantage data:**
  TEP members said that Medicare Advantage data are of limited usefulness because some plans do not submit their data.

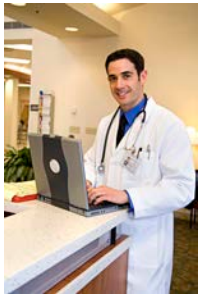
- **Prior authorization:**
  In the past, hemodynamic benefit had to be demonstrated before inotropic therapy was approved as part of a certificate of medical necessity (CMN) but this requirement no longer exists. TEP members thought that a prior authorization requirement would be for the services and not the drug itself so if the drugs require prior authorization, services would not need to be authorized as the drug authorization should be sufficient. In addition, one TEP member said they were not sure how much prior authorization would help because for most of the covered drugs, alternate options for treatment are not available.

Appendix A: Materials presented to TEP

Home Infusion Therapy

Technical Expert Panel Meeting

August 8, 2018



Agenda

Time	Topic
9:00 – 9:20am	**Welcome and introductions**
9:20 – 10:00am	Understanding who uses home infusion therapy
10:00 – 10:30am	Trends in home infusion therapy 2012-2017
10:30 – 10:45am	Break
10:45 – 11:00am	Drugs covered under the Medicare home infusion benefit
11:00 – 12:15pm	Role of home infusion suppliers
12:15 – 1:30pm	Lunch
1:30 – 3:00pm	Payment for Medicare home infusion services
3:00 – 3:15pm	Break
3:15 – 3:50pm	Non-FFS Medicare infusion coverage/prior authorization
3:50 – 4:00pm	Wrap-up & logistics

Introductions

- Welcome!
- Thank you for participating in this Medicare Home Infusion Technical Expert Panel (TEP).
- Abt Team:
  - Alan White, PhD
  - Morris Hamilton, PhD
  - Michael Plotzke, PhD
  - Elizabeth Campbell, RN
  - Allison Muma, MHA
  - Seyoun Kim, MHS

TEP Members

Invitee	Organization
William Bolgar, PharmD	Coram CVS Specialty Infusion Services
Paul Celano, MD	Greater Baltimore Medical Center
Logan E. Davis, PharmD, MBA	Vital Care Home Infusion Services
Randy Falkenrath, MBA	Humana Specialty Pharmacy
Lisa Gorski, RN	Wheaton Franciscan Healthcare
Alan Koterba, MD, PhD	Allergy Associates of the Palm Beaches
Rose Madden-Baer, RN	Visiting Nurse Service – New York
Kim Neuman, MS	Medicare Payment Advisory Commission
Mihir (Mitch) Patel, PharmD	Cigna Healthspring
Lynn Warner Stevenson, MD	Vanderbilt University Medical Center
Kendall Van Pool	National Home Infusion Association

Guidelines for the TEP

- Provide input to support development of a Medicare home infusion benefit.
  - The TEP is designed to inform rulemaking for the home infusion benefit legislated in the 21st Century Cures Act.
- Comments to CMS on proposals in the Draft Rule will not be discussed today but can be submitted via the rulemaking comment process.
- Representatives from CMS will be observing but not participating in the meeting.
- The meeting will be recorded for note-taking purposes.
  - CMS may publish notes publicly.
  - Names will be de-identified in the notes if released publicly.

Goals for the TEP

- We seek input from the TEP to help develop policies for these issues and to identify any other implementation issues that should be addressed.
- In some cases, we seek input on whether aspects of the Bipartisan Budget Act of 2018 that should be used for the benefit developed under the 21st Century Cures Act.
  - Temporary transitional payments mandated by section 50401 of the BBA of 2018.
  - We do not seek input on CMS proposals that are out for public comment, which are in rulemaking

Key Issues for Today

- We divide today's agenda into two topics:
  - Learning more about home infusion therapy (before first break).
    - Understanding who uses home infusion therapy.
    - Current and future trends in home infusion therapy.
  - Implementation of the home infusion therapy benefit (remainder of day).
    - Drugs covered under Medicare home infusion benefit.
    - Role of home infusion suppliers.
    - Payment for Medicare home infusion services.
    - Non-Medicare FFS home infusion therapy, especially regarding prior authorization requirements.

TEP Glossary: Definitions from 21st Century Cures Act

- Home infusion therapy services: Services explicitly covered under the Cures Act are:
  - Professional services, including nursing services, furnished in accordance with the plan.
  - Training and education (not otherwise paid for as durable medical equipment).
  - Remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.
- Home infusion drugs –A parenteral drug or biological administered:
  - Either intravenously, or subcutaneously with an administration period of 15 minutes or more.
  - At an individual's home through a DME pump

TEP Glossary: Definitions from 21st Century Cures Act

- Qualified home infusion supplier –A pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that:
  - Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;
  - Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;
  - Is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and
  - Meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

TEP Glossary: Bipartisan Budget Act of 2018 (BBA2018)

- BBA2018 establishes a home infusion therapy services temporary transitional payment that will begin on January 1, 2019 and end on the day before the date of the implementation of the payment system being developed under the 21st Century Cures Act.

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Understanding Who Uses Home Infusion Therapy

Purpose of Section:

To learn more about the demographic and clinical reasons for home infusion and to understand who might switch to home infusion after implementation of the Medicare home infusion therapy benefit.

Topics

- Background
  - Characteristics of existing home infusion users from 2017 Medicare Fee-For-Service (FFS) claims data.
- MCG Health Home Infusion Therapy Guidelines
  - What factors are important when referring a patient to home infusion therapy?
- Switching to Medicare home infusion therapy from the non-home setting.

Background: Medicare FFS Home Infusion Therapy Users

- Group users by Bipartisan Budget Act 2018 (BBA2018) drug categories (see Slide 33 for specific drugs)
  - Category 1: Anti-Infective, Cardiovascular, Pain, Other.
  - Category 2: Subcutaneous Immune Globulin and not otherwise classified.
    - *Because much of the not otherwise classified utilization is likely associated with the Cuvitru rollout, the "not otherwise classified" drug codes are grouped with Category 2 drugs for analysis.*
  - Category 3: Oncology.
- Users of multiple categories are grouped with the higher category.
  - e.g., a user of Category 1 and 2 drugs but not Category 3 will be grouped with Category 2.

Background: Medicare FFS Home Infusion Therapy Users

- Among Medicare FFS beneficiaries, home infusion users tend to be:
  - young (age<75),
  - white, and
  - located in urban areas.
- Most Medicare FFS home infusion users reside east of the Mississippi River. CMS Regions 1 through 5 represent about 70% of all users.
- Medicare FFS home infusion users are very sick.
  - Roughly half die within 3 years of use.
  - Less so for immune globulin (Category 2) users.

Background: Who uses home infusion therapy?

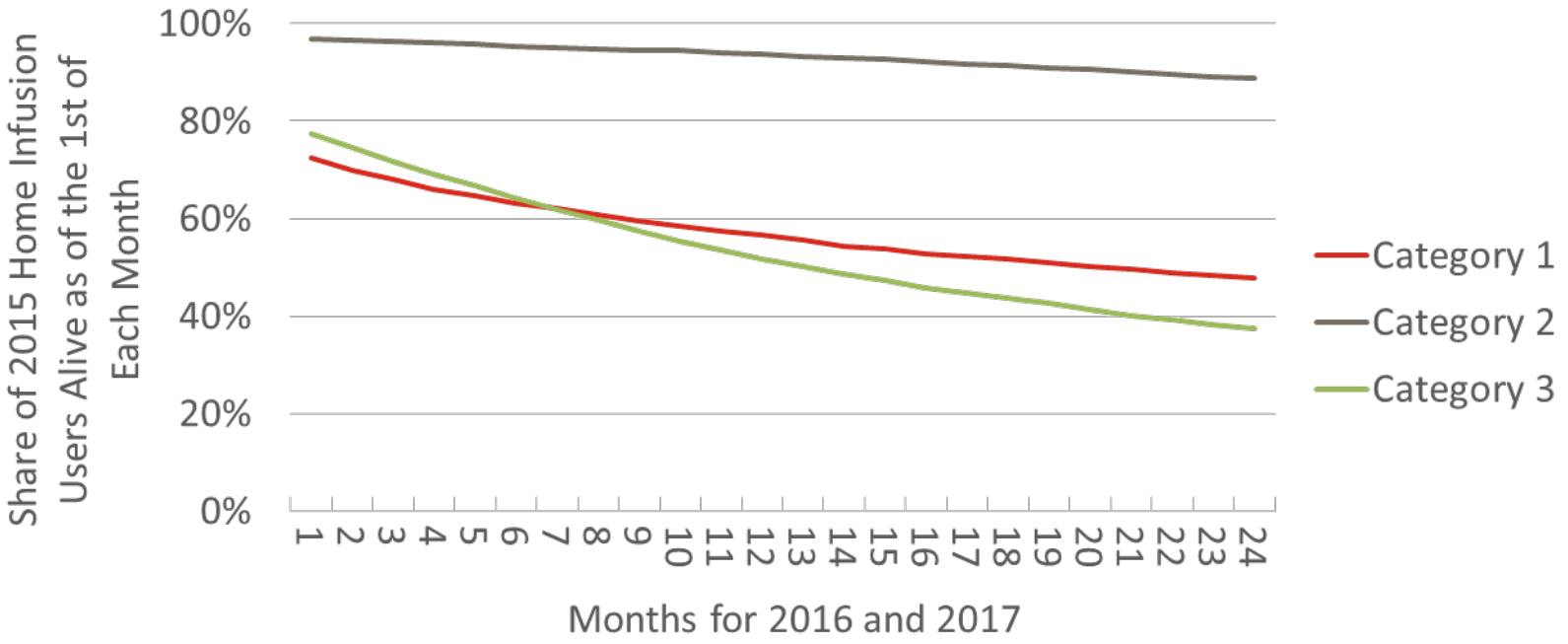
	BBA2018 Drug Category						All 2017 FFS Users	
	1		2		3			
	N	%	N	%	N	%	N	%
Under 65	2,519	41.0%	1,770	26.4%	862	14.5%	5,151	27.4%
65-74	2,304	37.5%	3,280	48.9%	3,323	56.0%	8,907	47.4%
75-84	1,087	17.7%	1,410	21.0%	1,542	26.0%	4,039	21.5%
85+	210	3.4%	238	3.5%	192	3.2%	640	3.4%
Male	3,230	52.6%	1,531	22.8%	3,372	56.8%	8,133	43.3%
Female	2,890	47.1%	5,167	77.0%	2,547	42.9%	10,604	56.4%
White	4,146	67.5%	6,403	95.4%	4,967	83.7%	15,516	82.6%
Black	1,458	23.7%	85	1.3%	574	9.7%	2,117	11.3%
Other	516	8.4%	210	3.1%	378	6.4%	1,104	5.9%
Urban	5,067	82.5%	5,720	85.2%	4,574	77.1%	15,361	81.8%
Rural	1,044	17.0%	976	14.5%	1,332	22.5%	3,352	17.8%
Total	**6,141**	**100.0%**	**6,713**	**100.0%**	**5,932**	**100.0%**	**18,786**	**100.0%**

Background: Where are home infusion therapy users?

CMS Region of User's Address	Share of Users by BBA2018 Drug Category			All 2017 FFS Users	
	1	2	3	N	%
1 – CT, MA, ME, NH, RI, VT	5.5%	5.0%	1.3%	748	4.0%
2 – NJ, NY, PR, VI	9.8%	6.3%	19.4%	2,174	11.6%
3 – DC, DE, MD, PA, VA, WV	11.8%	8.8%	25.8%	2,841	15.1%
4 – AL, FL, GA, KY, MS, NC, SC, TN	23.9%	32.0%	15.0%	4,503	24.0%
5 – IL, IN, MI, MN, OH, WI	16.2%	10.8%	19.0%	2,849	15.2%
6 – AR, LA, NM, OK, TX	13.8%	11.1%	4.3%	1,852	9.9%
7 – IA, KS, MO, NE	4.9%	7.0%	4.1%	1,017	5.4%
8 – CO, MT, ND, SD, UT, WY	1.8%	3.4%	1.8%	449	2.4%
9 – AS, AZ, CA, GU, HI, NV, MP	9.3%	13.0%	6.1%	1,810	9.6%
10 – AK, ID, OR, WA	2.5%	2.3%	2.7%	470	2.5%
Total	**100.0%**	**100.0%**	**100.0%**	**18,786**	**100.0%**

Background: How healthy are home infusion therapy users?

- 2015 users alive by December 1, 2017
  - Category 1: 47.7%
  - Category 2: 88.9%
  - Category 3: 37.6%



MCG Health
Home Infusion Therapy Guidelines

- As part of its 22nd Edition Home Infusion Therapy guidelines, MCG Health identified three types of patient attributes that should be assessed prior to initiating home infusion therapy.

1. Patient health and clinical appropriateness for treatment.
    a) What makes a patient appropriate for treatment?
    b) Home versus other settings?
2. Patient home environment.
3. Caregiver abilities.

MCG Health
Home Infusion Therapy Guidelines

Item 1:
Patient health and clinical appropriateness for treatment

- What factors should be considered for home infusion therapy?
  - Patient's overall health? Comorbidities?
  - Specific medical condition requiring treatment?
  - Specific drug used for treatment?
  - Expected quality of care at home versus other settings (hospital outpatient departments or physician offices)?
  - Others?
- Are some factors more important than others?

MCG Health
Home Infusion Therapy Guidelines

Item 2:
Patient home environment

- What factors should be considered for home infusion therapy?
  - Utilities: refrigeration, electricity, and telephone?
  - Cleanliness and safety?
  - Emergency transportation?
  - Health status of others living in home?
  - Others?
- Are some factors more important than others?

MCG Health
Home Infusion Therapy Guidelines

Item 3:
Caregiver abilities

- What factors should be considered for home infusion therapy?
  - Ability of caregiver?
  - Willingness of caregiver?
  - Emotional stability of caregiver?
  - Others?
- Are some factors more important than others?

Switching to Home Infusion Therapy After the 21st Century Cures Act

- How much switching does the TEP anticipate?
- Who will switch?
  - By beneficiary characteristics?
  - By therapeutic class?
- Timing of switch?
  - Will the decision to switch be gradual or immediate?
- Which group is more likely to switch?
  - Those starting their infusion therapy with a choice between home versus non-home setting?
  - Current infusion therapy users in a non-home setting?

Switching to Home Infusion Therapy After the 21st Century Cures Act

New patient incentives

- Services are now clearly defined for all enrollees.
- Lower out-of-pocket costs for some users, e.g. switchers from IVIG to SCIG.
  - Makes home setting more attractive.
- Others?

New supplier incentives

- Any provider can become a home infusion therapy supplier; physicians, home health agencies, etc. can benefit in addition to DME.
- Coverage is now explicitly reimbursed and more clearly defined.
- Others?

Agenda

Time	Topic
9:00 – 9:20am	Welcome and introductions
9:20 – 10:00am	Understanding who uses home infusion therapy
10:00 – 10:30am	**Trends in home infusion therapy 2012-2017**
10:30 – 10:45am	Break
10:45 – 11:00am	Drugs covered under Medicare home infusion benefit
11:00 – 12:15pm	Role of home infusion suppliers
12:15 – 1:30pm	Lunch
1:30 – 3:00pm	Payment for Medicare home infusion services
3:00 – 3:15pm	Break
3:15 – 3:50pm	Non-FFS Medicare infusion coverage/prior authorization
3:50 – 4:00pm	Wrap-up & logistics

Trends in Home Infusion Therapy 2012-2017

Purpose of Section:

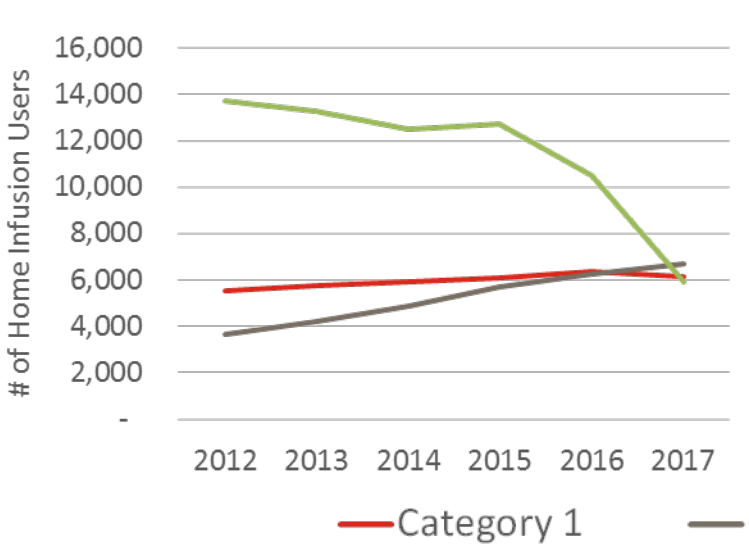
To discuss recent patterns in utilization and expenditures, and how they inform patterns in the coming years.

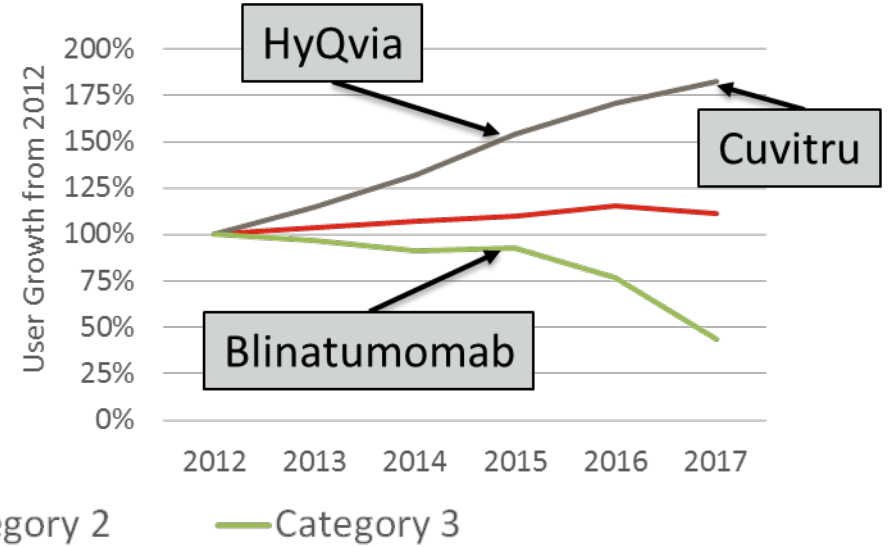
Topics

- Recent patterns in home infusion utilization and drug spending.
- How are these patterns expected to change in the coming years, especially after the implementation of the 21st Century Cures Act?

Users of Home Infusion Therapy 2012-2017

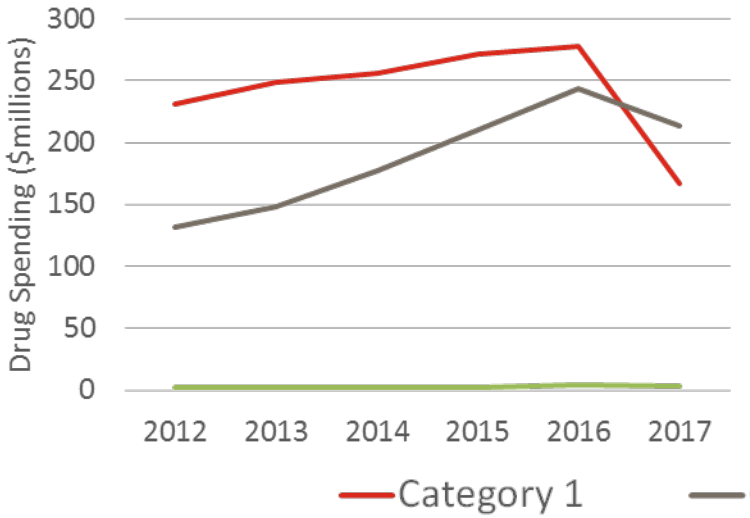
- The number of Category 1 users grew slightly.
- Immune globulin (Category 2) *rose* by 82.5%.
- Oncology (Category 3) *fell* by 56.7%; likely because of immunotherapy adoption.
- Approved HyQvia (Sep 2014), Blinatumomab (Dec 2014), and Cuvitru (Sep 2016).

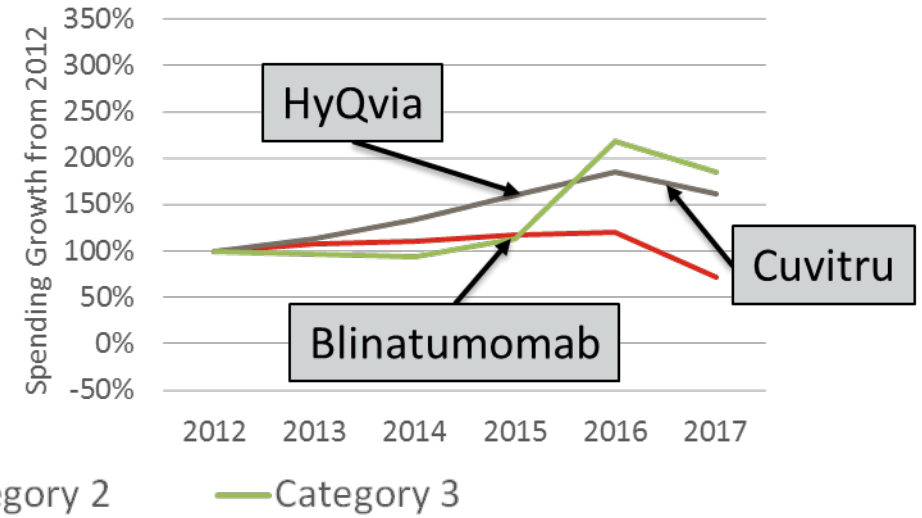




Drug Spending for Home Infusion Therapy 2012-2017

- At $27,116 and $31,757 per user in 2017, Categories 1 and 2 drug expenditures are substantially higher than Category 3 at $569 in 2017.
- Part B re-pricing to Average Sale Price + 6% began January 2017.
  - Large decrease in drug spending for Category 1, in particular for milrinone lactate.
  - Relatively smaller reduction in drug spending for Categories 2 and 3.





Trends in Home Infusion Therapy 2012-2017

- **Takeaway:** because there are a small number of very expensive users, utilization and spending fluctuates when:
  - Drugs are approved.
  - Clinical practice guidelines change.
    - What is the justification for immune globulin growth?
    - Transition from chemotherapy to immunotherapy.
  - Government reimbursement or regulations change.
  - Others?
- Are similar changes expected in the coming years?

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Drugs Covered Under the Home Infusion Benefit

Purpose of Section:

To understand the infusion drugs that will be covered under the 21st Century Cures Act and BBA2018 and identify any potential gaps.

Topics

- Review of Cures Act definition of covered drugs.
- Review of BBA2018 covered drugs.
- Discussion of additional analyses.

Drugs Covered Under the Home Infusion Benefit

- The 21st Century Cures Act defines home infusion drugs as a parenteral drug or biological administered:
  - Either intravenously, or subcutaneously with an administration period of 15 minutes or more.
  - At an individual's home through a DME pump.
- Drugs not included in home infusion benefit:
  - Drugs that are identified on the self-administered drug exclusion list, which is set by Medicare Administrative Contractors (MACs).
  - Insulin pumps.

Bipartisan Budget Act of 2018: Covered Home Infusion Drugs

- Drugs covered under local coverage determinations for external infusion pumps.
  - Grouped by therapeutic class into three payment categories.

BBA2018 Category	HCPCS Code	Drug Category	Description
1	J0285	Anti-fungal	Amphotericin B 50 mg
1	J0287	Anti-fungal	Amphotericin B, lipid complex 10 mg
1	J0288	Anti-fungal	Amphotericin B, cholesteryl sulfate complex 10 mg
1	J0289	Anti-fungal	Amphotericin B, liposome 10 mg
1	J0133	Anti-viral	Injection, Acyclovir, 5 mg
1	J1455	Anti-viral	Foscarnet sodium per 1,000 mg
1	J1570	Anti-viral	Ganciclovir sodium 500 mg
1	J1250	Cardiovascular	Dobutamine HCl per 250 mg
1	J1265	Cardiovascular	Injection, Dopamine HCl, 40 mg
1	J1325	Cardiovascular	Epoprostenol 0.5 mg
1	J2260	Cardiovascular	Milrinone lactate 5 mg
1	J3285	Cardiovascular	Injection, treprostinil, 1 mg

Bipartisan Budget Act of 2018: Covered Home Infusion Drugs

BBA2018 Category	HCPCS Code	Drug Category	Description
1	J0895	Heavy metal poisoning	Deferoxamine mesylate 500 mg
1	J1457	Hypercalcemia related to chemo	Gallium nitrate 1 mg
1	J1170	Pain	Hydromorphone HCl up to 4 mg
1	J2175	Pain	Meperidine HCl per 100 mg
1	J2270	Pain	Morphine sulfate up to 10 mg
1	J2274	Pain	Morphine sulfate, preservative-free 10 mg
1	J2278	Pain	Injection, ziconotide, 1 mcg
1	J3010	Pain	Fentanyl citrate 0.1 mg
2	J1555 JB	Immune globulin	Injection, immune globulin, (Cuvitru), 100 mg
2	J1559 JB	Immune globulin	Injection, immune globulin (Hizentra), 100 mg
2	J1561 JB	Immune globulin	Injection, immune globulin, (Gamunex-C/Gammaked), non-lyophilized (e.g., liquid), 500 mg
2	J1562 JB	Immune globulin	Injection, immune globulin (Vivaglobin), 100 mg
2	J1569 JB	Immune globulin	Injection, immune globulin, (Gammagard Liquid), Non-lyophilized, (e.g., liquid), 500 mg
2	J1575 JB	Immune globulin	Hyaluronidase, (Hyqvia) 100 mg

Bipartisan Budget Act of 2018: Covered Home Infusion Drugs

BBA2018 Category	HCPCS Code	Drug Category	Description
3	J9000	Oncology	Doxorubicin HCL 10 mg
3	J9039	Oncology	Blinatumomab 1 microgram
3	J9040	Oncology	Bleomycin sulfate 15 units
3	J9065	Oncology	Cladribine per mg
3	J9100	Oncology	Cytarabine 100 mg
3	J9190	Oncology	Fluorouracil 500 mg
3	J9200	Oncology	Floxuridine 500 mg
3	J9360	Oncology	Vinblastine sulfate 1 mg
3	J9370	Oncology	Vincristine sulfate 1 mg
Other	J7999	Not otherwise classified	Compounded drug, not otherwise classified
Other	J7799	Not otherwise classified; includes Cuvitru	NOC drugs, other than inhalation drugs, administered through DME

- Infusion drugs not otherwise classified are assigned to the most appropriate category if the Medicare Administrative Contractor that processes DME claims determines them to be covered drugs.

Home Infusion Drugs Covered: Questions for TEP Discussion

- What feedback do TEP members have on the list of drugs covered under BBA2018?
  - Are there any additional drugs that meet the 21st Century Cures Act criteria but are not listed under BBA2018?
  - Are there any additional analyses to be conducted to identify drugs that should be covered?
  - Do the three categories make sense clinically?
    - Based on Current Procedural Terminology (CPT) codes.
    - Different methods for grouping?

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Role of Home Infusion Suppliers

Purpose of Section:

To understand the role of the home infusion therapy suppliers.

Topics

- 21st Century Cures Act provisions.
- Relationship between DME and home infusion benefits.
- Understanding supplier roles in delivering home infusion therapy and monitoring patients.

Role of Home Infusion Suppliers: 21st Century Cures Act Provisions

- Patient has to be under care of applicable provider:
  - physician,
  - nurse practitioner, or
  - physician assistant.
- Patient must receive therapy in the individuals home.
- Patient has to be under a plan of care that is established and periodically reviewed by a physician.

Role of Home Infusion Suppliers: 21st Century Cures Act Provisions

- Services explicitly covered by Cures Act are:
  - Professional services, including nursing services, furnished in accordance with the plan.
  - Training and education (not otherwise paid for as durable medical equipment).
  - Remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.
- Necessary for the safe and effective administration of home infusion drugs.

Relationship Between Home Infusion and Medicare DME Benefit

- Limited number of home infusion drugs covered through the DME benefit:
  - Drug must be necessary for the effective use of an external infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug.
  - The drug being used with the pump must be reasonable and necessary for the treatment of an illness or injury.
- Only certain types of infusion pumps are covered through the DME benefit.

HCPCS Code	Description
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single or multi-channel
K0455	Infusion pump used for uninterrupted parenteral administration of medication, (e.g., epoprostenol or treprostinol)

Relationship Between Home Infusion and Medicare DME Benefit

- Home infusion supplier does not need to be the DME supplier.
  - Per the 21st Century Cures Act, a qualified home infusion therapy supplier can be a "pharmacy, physician, or other provider of services."
- Do TEP members have comments on the relationship between the DME benefit and the home infusion benefit?
  - Now?
  - Under the 21st Century Cures Act?

Role of Home Infusion Suppliers

- We would like to better understand the roles of suppliers when delivering home infusion therapy, both now and under the 21st Century Cures Act.
- The remainder of the section is designed for us to learn more about:
  - The role nurses or other professionals play,
  - The role DME suppliers play, and
  - The use of remote monitoring and monitoring services.

Role of Home Infusion Suppliers: Nurses

RN Responsibilities for Home Infusion Patients*
1. Administering medications
2. Assessing for adverse drug reactions
3. Ensuring that product labeling is clear and accurate
4. Changing site dressings and flushing line
5. Assessing home safety
6. Assessing psychosocial status
7. Assessing status of venous access device, response to infusion, and potential side effects/complications
8. Managing laboratory tests
9. Facilitating access to other caregivers (e.g., therapists, dieticians, social workers) as appropriate
10. Arranging referrals for financial assistance as needed
11. Communicating with other team members
12. Revising treatment plans as needed
13. Documenting progress and patient status

Key questions:

(1) Is this list complete?

(2) How much time do these activities take to complete?

(3) How frequently do these activities occur?

(4) Role of other professionals?

**Source: MCG Health Home Infusion Therapy Guidelines and clinical expert input.*

Role of Home Infusion Suppliers: Questions for TEP Discussion

- How long does it take to train and educate patients about the provision of infusion drugs?
  - How does this vary based on patient characteristics, home environment, and patient/caregiver needs?
  - How does this vary based on intensity of the drug/complexity of drug administration? (e.g., for medications with continuous administration; for life-sustaining medications)?
- How long is a typical visit?
  - Is this likely to be constant across all visits or higher for initial visits?
  - For how long are these professional services necessary?

Role of Home Infusion Suppliers: Remote Monitoring and Monitoring

- What is a reasonable and necessary amount of time for remote monitoring, and monitoring services?
  - What types of remote monitoring and monitoring services do home infusion patients require? For how long are these services necessary?
- How often should remote monitoring occur?
  - How does the need for remote monitoring and monitoring services vary based on patient characteristics, home environment, and patient/caregiver needs?
  - How does the need vary based on intensity of the drug/complexity of drug administration? (e.g., for medications with continuous administration; for life-sustaining medications)?

Role of Home Infusion Suppliers: Remote Monitoring and Monitoring

- Is the proposed home health definition of remote monitoring consistent with your understanding?

  "Remote patient monitoring is defined as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home [infusion therapy supplier]."

- How is remote monitoring typically used? Most frequently used types?

Role of Home Infusion Suppliers: Remote Monitoring and Monitoring

- Home infusion therapy suppliers must ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.
  - Would daily monitoring be required for some high-risk patients through remote monitoring?
  - Conversely, lower risk patients may only need monitoring services while the supplier is visiting and may not require remote monitoring.

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Payment for Home Infusion Services

Purpose of Section:

To understand how home infusion services will be paid for under the 21st Century Cures Act; to understand the payment provisions of BBA2018 and discuss issues related to payment for home infusion services.

Topics

- 21st Century Cures Act payment provisions.
- BBA2018 payment provisions.
- Other adjustments to payment rates.

Payment for Home Infusion Services

- 21st Century Cures Act specifies that a payment unit is "for each infusion drug administration calendar day in the individual's home."
  - Payment rates may be adjusted based on "patient acuity and complexity of drug administration."
  - Payment amount "shall not to exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day."

Payment for Home Infusion Services

- In developing the payment system, the 21st Century Cures Act states that CMS may consider:
  - Costs of furnishing infusion therapy in the home,
  - Payment amounts for similar items and services under Medicare, and
  - Medicare Advantage payment amounts.
- Payment methodology specified in BBA2018 may also be informative.

BBA2018: Payment Methodology

- Establishes three distinct rates for billing home infusion services.
  - Reimbursement methodology is aligned with the 21st Century Cures Act, which limits payment for home infusion to the cost of infusion in a physician's office.
  - Payment rates are mapped to specific J-codes used to bill Part B DME infusion drugs by therapy type.
- Reimbursement levels based on costs of 4 hours of infusion in a physician's office for the appropriate HCPCS codes.

BBA2018: Payment Rates

BBA2018 Category	Payment Codes	2018 Payment Rates	Total Payment (Rate1+3*Rate2)
1	96365 96366	$74.16 $22.32	$141.12
2	96369 96370	$176.76 $15.84	$224.28
3	96413 96415	$144.72 $31.68	$239.76

Payment Rates: Topics for TEP Discussion

- Are there sources of information on costs of providing home infusion therapy or other sources that CMS should consider as it develops payment rates?
- Do the three payment categories used under BBA2018 adequately reflect the therapy type and complexity of the drug administration?
  - Would they be a reasonable basis for payment under the 21st Century Cures Act?
  - What other methods should CMS consider to account for patient acuity and complexity of administration?

Other Adjustments to Payment Rates

- Other potential adjustments specified in 21st Century Cures Act:
  - Geographic wage index.
  - Outliers.
- Annual updates based on percent increase in urban Consumer Price Index (CPI), reduced by a productivity adjustment that is calculated based on an economy-wide productivity measure.

Other Adjustments to Payment Rates: Outliers

- Given the payment methodology, do TEP members believe there will be patients with outlier costs?
  - If so, what types of patients?
  - What would be the most appropriate method for providing outlier payments in the home infusion benefit?
- Do TEP members have feedback on the methodology for annual updates to home infusion payment rates?

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Non-FFS Medicare Infusion Coverage

Purpose of Section:

To consider "the standards of care [and payments] for home infusion therapy established by Medicare Advantage under part C and in the private sector."

Topics

- 2014-2016 Truven Health MarketScan® Research Commercial Database review of home infusion therapy utilization and enrollee characteristics.
- Discussion of home infusion therapy landscape in Medicare Advantage and private sector.
- Discussion of prior authorization.

**MarketScan is a registered trademark of Truven Health Analytics, part of the IBM Watson Health business.*

Identifying Home Infusion Therapy Services with MarketScan Data

- Commercial payer data; ages 65 and younger.
- Years 2014, 2015, and 2016.
- Identified 16,881 home infusion users using the 37 home infusion drug codes (see Slide 33 for specific drugs).

Identifying Home Infusion Therapy Services with MarketScan Data

- Identified home infusion therapy services records that occur “around” home infusion drug records.
  - “Around” defined as from the beginning of drug record to one week after end of drug record.
  - Use 2017 National Home Infusion Association (NHIA) Quick Coding Reference to identify home infusion therapy records; exclude codes for TPN or hydration, which are not covered.
- 82.2% (13,874) of home infusion drug users have home infusion therapy services claims totaling almost $22 million.

MarketScan Data by Drug Category

	BBA2018 Drug Category						MarketScan Data Users	
	1		2		3			
	N	%	N	%	N	%	N	%
18 – 34	682	14.6%	1,052	17.9%	223	3.5%	1,957	11.6%
35 – 44	698	15.0%	982	16.7%	589	9.3%	2,269	13.4%
45 – 54	1,342	28.7%	1,556	26.5%	2,013	31.8%	4,911	29.1%
55 – 64	1,934	41.4%	2,262	38.4%	3,480	55.0%	7,676	45.5%
65+	14	0.3%	29	0.5%	25	0.4%	68	0.4%
Male	2,176	46.6%	2,105	35.8%	3,531	55.8%	7,812	46.3%
Female	2,494	53.4%	3,776	64.2%	2,799	44.2%	9,069	53.7%
Urban	3,901	83.5%	5,236	89.0%	5,218	82.4%	14,355	85.0%
Rural	769	16.5%	645	11.0%	1,112	17.6%	2,526	15.0%
Total	**4,670**	**100.0%**	**5,881**	**100.0%**	**6,330**	**100.0%**	**16,881**	**100.0%**

Private Market Users versus Medicare FFS Users

- Relative to the 2017 Medicare FFS users, the MarketScan data users from 2014 – 2016 are:
  - Younger,
  - More male,
  - Less rural, and
  - More likely to use Category 3 drugs.

	MarketScan Data Users		All 2017 FFS Users	
	N	%	N	%
Under 65	16,813	99.6%	5,151	27.4%
65-74	68	0.4%	8,907	47.4%
75-84	---	---	4,039	21.5%
85+	---	---	640	3.4%
Male	7,812	46.3%	8,133	43.3%
Female	9,069	53.7%	10,604	56.4%
Urban	14,355	85.0%	15,361	81.8%
Rural	2,526	15.0%	3,352	17.8%
Category 1	4,670	27.7%	6,141	32.7%
Category 2	5,881	34.8%	6,713	35.7%
Category 3	6,330	37.5%	5,932	31.6%
Total	**16,881**	**100.0%**	**18,786**	**100.0%**

Private Market Users versus Medicare FFS Users

- Differences by type of payer?
  - Medicare Advantage (not in MarketScan data) versus Medicare FFS?
  - Medicare versus Non-Medicare?
- Differences by type of patient?
  - Age?
    - Younger patients are more likely to receive transplants.
  - Rurality?
    - Less commuting in urban areas but patients may also have a weaker incentive to receive infusion therapy at home if facilities are nearby.
  - Others?

Identifying Home Infusion Therapy Services with MarketScan Data

- Below are the top ten most expensive home infusion therapy S-Codes by total payments across all 2014-2016 claims.
- All codes represent a per diem payment and cover:
  - Administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately).

Top Ten Most Expensive Home Infusion Therapy S-Codes	
Codes	**Description**
1 – S9338	Immunotherapy
2 – S9330	Continuous (twenty-four hours or more) chemotherapy infusion
3 – S9348	Sympathomimetic/inotropic agent infusion therapy (e.g., dobutamine)
4 – S9379	Infusion therapy, not otherwise classified
5 – S9328	Implanted pump pain management infusion
6 – S9347	Uninterrupted, long-term, controlled rate intravenous or subcutaneous infusion therapy (e.g., epoprostenol)
7 – S9329	Chemotherapy infusion
8 – S9326	Continuous (twenty-four hours or more) pain management infusion
9 – S9500	Antibiotic, antiviral, or antifungal therapy; once every 24 hours
10 – S9325	Pain management infusion

Identifying Home Infusion Therapy Services with MarketScan Data

- Given these payment values, what services do these S-Codes typically describe?

Top Ten Most Expensive Home Infusion Therapy S-Codes					
	Payment of Covered Benefits				
Codes	P10	p25	Median	p75	p90
1 – S9338	$13.64	$45.00	$69.21	$79.00	$172.15
2 – S9330	20.33	27.00	37.50	75.00	116.00
3 – S9348	8.57	14.17	44.24	68.35	96.00
4 – S9379	8.67	30.00	55.00	65.00	90.00
5 – S9328	8.14	15.00	45.00	45.00	45.00
6 – S9347	6.43	40.00	55.00	75.00	75.00
7 – S9329	21.96	34.67	58.33	92.75	146.74
8 – S9326	5.54	10.50	41.00	57.00	70.00
9 – S9500	9.06	15.30	47.69	80.00	180.17
10 – S9325	7.86	23.75	65.10	68.29	100.00
Total	**$10.09**	**$27.67**	**$46.35**	**$75.00**	**$126.00**

Prior Authorization

- Based on a review of private insurance guidelines, we found that prior authorization is a primary tool for commercial plans.
- The 21st Century Cures Act gives the Secretary discretion to consider prior authorization requirements for home infusion therapy services.
  - Private payers generally require prior authorization, although not necessarily for all drugs (MedPAC, 2012).
- MedPAC believes that management controls such as prior authorization would be necessary to ensure that home infusion is provided appropriately.

Prior Authorization

- CMS will maintain the discretion to decide whether certain drugs or frequency in visits require prior authorization before therapy can be covered.
  - The emphasis would be on the appropriateness of the drug and the necessity of associated professional services and not the site of care.

Prior Authorization: Topics for TEP Discussion

- What are the tradeoffs associated with a prior authorization requirement?
  - Could a prior authorization requirement be effective in ensuring safe and appropriate utilization?
  - If so, for what types of patients or infusion drugs would a prior authorization make the most sense?
  - What would the costs of a prior authorization requirement be?
- What elements should be required for prior authorization?
  - If so, how would a prior authorization policy be administered?

Agenda

Time	Topic
9:00 – 9:20am	Welcome and introductions
9:20 – 10:00am	Understanding who uses home infusion therapy
10:00 – 10:30am	Trends in home infusion therapy 2012-2017
10:30 – 10:45am	Break
10:45 – 11:00am	Drugs covered under Medicare home infusion benefit
11:00 – 12:15pm	Role of home infusion suppliers
12:15 – 1:30pm	Lunch
1:30 – 3:00pm	Payment for Medicare home infusion services
3:00 – 3:15pm	Break
3:15 – 3:50pm	Non-FFS Medicare infusion coverage/prior authorization
3:50 – 4:00pm	**Wrap-up & logistics**

Wrap-Up and Logistics

- For additional questions, please contact:
  - Seyoun Kim (Seyoun_Kim@abtassoc.com)
  - Allison Muma (Allison_Muma@abtassoc.com)
- Logistics:
  - Expense reimbursement.
  - We will prepare notes from today's TEP and will either post publicly or redistribute.

Wrap-Up and Logistics

Thank you for your participation today!

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