THE INS & OUTS OF HOME INFUSION THERAPY ACCREDITATION

Presenters:
Lisa Meadows, MSW
Clinical Compliance Educator
ACHCU

Lynn Labarta
CEO and Founder
Imark Billing
OBJECTIVES

- Discuss the requirements for Home Infusion Therapy (HIT) services
- Discuss the differences between HIT and Home Health, Private Duty Nursing, Infusion Nursing and Infusion Pharmacy
- Discuss billing requirements for Home Infusion Therapy
MEDICARE BENEFITS

- Medicare Part A:
  - Covers inpatient hospital care, skilled nursing facility, hospice, lab tests, surgery, home health care.

- Medicare Part B:
  - Covers durable medical equipment, out-patient services, physician visits, and some preventive services.

- Medicare Part C:
  - Alternative to traditional Medicare otherwise known as Medicare Advantage Plans

- Medicare Part D:
  - Prescription drug coverage
HOME INFUSION THERAPY BENEFIT

- Home Infusion Therapy benefit (HIT)
  - New Medicare Part B benefit effective January 1, 2021
  - Limitations to medications covered under the HIT benefit
  - Patient Part B co-pay is applicable
HOME INFUSION THERAPY SERVICES
HOME INFUSION THERAPY

- Home Infusion Therapy (HIT)
  - Section 1834(u)(1) of the Social Security Act (the Act), as added by Section 5012 of the 21st Century Cures Act (Pub. L. 144-255), established a new Medicare HIT benefit under Medicare Part B. The Medicare HIT benefit is for coverage of HIT services for certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is a DME item.
  - This benefit is effective January 1, 2021.
  - Involves the parenteral administration of drugs or biologicals in the patient’s home; not in the hospital setting, clinic setting, ambulatory infusion clinics, or skilled nursing facilities.
  - This is a new payment for the professional service, training and education, and monitoring needed to administer the home infusion drug in the home.
HOME INFUSION THERAPY

- Who can qualify as a HIT supplier?
- A pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of 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 approved organization; and
  - Meets such other requirements as the Secretary determines appropriate
HOME INFUSION THERAPY

- The DME benefit covers three components: the external infusion pump, the related supplies, and the infusion drug.
  - Additionally, this benefit covers the related services required to furnish these items (e.g., pharmacy services, delivery, equipment set up, maintenance of rented equipment, and training and education on the use of the covered items) by an eligible DME supplier.
- No payment is made under the HIT benefit for these DME items and services.
HOME INFUSION THERAPY

- The new HIT benefit covers the service component, meaning the professional services, training and education (not otherwise covered under the DME benefit), and monitoring furnished by a qualified HIT supplier needed to administer the home infusion drug in the patient’s home.

- The service of the administration of the drug and/or biological must by provided by an RN, LPN/LVN, in accordance with state practice acts.
  - Skilled nurses may need additional training, experience, and/or competencies based on state scope of practice
  - May need additional policies or policy revisions based on changes in clinical practice
DME VS. HIT BENEFIT

DME VS. HIT BENEFIT

- The DME benefit is not changing and therefore DME providers who supply the pump, tubing, related supplies, medication, etc. do not need to obtain HIT accreditation as the HIT benefit does not cover and will not cover these items.

- Home Health and Private Duty Nursing agencies do not need to also become DME providers in order to obtain the pump, tubing, related supplies and medication; they may subcontract with a pharmacy or DME supplier for these supplies.
DME VS. HIT BENEFIT

- Qualified HIT suppliers can only bill and be paid for the HIT services furnished on the day on which a professional is physically present in the patient’s home and an infusion drug is being administered on such day.

- Medicare payment for an infusion drug administration calendar day is separate from the payment for DME items and services, therefore, a supplier could still be paid for DME items and services under the DME benefit, even if the supplier does not receive payment for home infusion therapy services under the HIT benefit.
DME VS. HIT BENEFIT

- The DME supplier is also responsible for delivery and set up of the equipment, as well as training and education on operation of the infusion pump.
- The DME benefit also covers pharmacy services (i.e., drug preparation and dispensing), including sterile compounding, that are associated with the furnishing of the home infusion drug.
DME VS. HIT BENEFIT

- Qualified HIT suppliers can only bill for HIT for days on which a professional is physically present in the patient’s home and an infusion drug is being administered.

- The HIT benefit is intended to be a separate payment from the amount paid under the DME benefit, explicitly covering the professional services that occur in the patient’s home, which could include services such as:
  - Training and education on care and maintenance of vascular access devices
  - Dressing changes and site care
  - Patient assessment and evaluation
  - Medication and disease management education
  - Monitoring/remote monitoring services
PATIENT QUALIFICATIONS FOR HIT

- The patient must be receiving a parenteral drug and/or biological that is administered intravenously or subcutaneously for an administration period of 15 minutes or more; and
- Through a pump that is an item of DME covered under the Medicare Part B DME benefit; and
- The drug and/or biological is administered in the home, cannot be administered in a hospital, clinic, ambulatory infusion clinic, or skilled nursing facility; and
- Patient does not have to be homebound to qualify for HIT or have an additional skilled need.
WHAT ACCREDITATION DO YOU NEED?
WHO SHOULD CONSIDER HIT ACCREDITATION?

- A Medicare certified Home Health agency may want to consider HIT accreditation if:
  - Want to diversify and expand into home infusion services for Medicare beneficiaries
  - Plans to bill Medicare Part B for the infusion nursing services
  - Expand potential patient data base as these patients do not need to be homebound or have another skilled service
WHO DOES NOT NEED HIT ACCREDITATION?

- A Medicare certified Home Health agency may not want to consider accreditation if:
  - Currently contracts their nursing staff to another provider that provides the infusion therapy and is HIT accredited
  - Wants to provide care provided under Part A for patients who will also receive care from a HIT accredited agency for the Part B infusion benefit
  - Provides infusion therapy to non-Medicare beneficiaries
  - Will not provide any of the approved medications that are not covered under the HIT benefit
WHO SHOULD CONSIDER HIT ACCREDITATION?

- A Private Duty Nursing agency, non-Medicare certified Home Health agency, may want to consider accreditation if:
  - Want to diversify and expand into home infusion services for Medicare beneficiaries
  - Plans to bill Medicare Part B for the infusion nursing services
WHO DOES NOT NEED HIT ACCREDITATION?

- A Private Duty agency, non-Medicare certified Home Health agency may not want to consider accreditation if:
  - Currently serves a very small infusion therapy population and does not want to diversify into Home Infusion Therapy
  - Wants to continue to provide infusion therapy but do not plan on billing Medicare Part B
  - Currently contracts their nursing staff to another provider that provides the infusion therapy
WHO SHOULD CONSIDER HIT ACCREDITATION?

- An Infusion Pharmacy with Infusion Nursing services or an Infusion Nursing agency may want to consider accreditation if:
  - They employ or contract for nursing services to administer infusion therapy services in the home and they plan to bill Medicare part B for the infusion nursing service
WHO DOES NOT NEED HIT ACCREDITATION?

- An Infusion Pharmacy with Infusion Nursing services or an Infusion Nursing agency may not want to consider accreditation if:
  - They plan on providing infusion therapy but do not plan on billing Medicare Part B; they are billing Medicaid, private insurance or the patient
DUAL ACCREDITATION

- Home Health, Private Duty Nursing, Infusion Nursing Services can continue to provide infusion therapy services, to non-Medicare beneficiaries, and not be HIT accredited.

- Agencies may also be accredited for both programs:
  - Home Health and HIT would be two separate surveys with different qualifying criteria.
  - Home Health would need to meet the Medicare Conditions of Participation, have a skilled need and be homebound.
  - HIT would need to meet the Conditions for Coverage and do not need to be homebound nor need another skilled service.
DUAL ACCREDITATION

- Private Duty Nursing (with or without other PD services) and HIT would be two separate surveys.
  - Private Duty Nursing (with or without other PD services) would not need to meet the Conditions for Coverage.
  - HIT would need to meet the Conditions for Coverage.
- Infusion Pharmacy that provides Infusion Nursing Services would be two separate surveys.
  - Infusion Nursing patients would not need to meet the Conditions for Coverage.
  - HIT would need to meet the Conditions for Coverage.

- Agencies can also choose to only be HIT accredited and not have their other program(s) accredited.
- Must be able to demonstrate Separation of Services.
SEPARATION OF SERVICES
SEPARATION OF SERVICES

- If you do not want the Conditions for Coverage and the ACHC HIT Standards for accreditation to apply to all of your patients then you must establish Separation of Services.
SEPARATION OF SERVICES

- Agency Operation:
  - Separate clinical records must be kept for patients receiving Infusion Nursing (IRN) and Home Infusion Therapy Supplier (HITS) services and for patients receiving Private Duty Nursing (PDN) and Home Infusion Therapy Supplier (HITS) services.
  - Additional policies address the requirements of providing home infusion therapy services.

- Consumer Awareness:
  - Marketing materials should be reviewed to verify that the materials note the differences between the services.
  - Written materials should clearly identify the Home Infusion Therapy Supplier service as separate and distinct from the Infusion Nursing and Private Duty Nursing services.
SEPARATION OF SERVICES

- Staff Awareness:
  - Staff should be able to identify the differences in services they provide under Home Infusion Therapy Supplier, Infusion Nursing, or Private Duty Nursing.
ELIGIBILITY FOR ACCREDITATION
ELIGIBILITY FOR HIT ACCREDITATION

- Be currently operating within the United States and/or its territories.
- Be licensed according to applicable state and federal laws and regulations and maintain all current legal authorization to operate.
- Have completed the Medicare Enrollment Application Form CMS-855B. N/A at this time.
- Have established policies and procedures.
- Demonstrate ability to provide all services needed by patients served.
- Have a staff Pharmacist, Physician or Registered Nurse. (Must have an RN to administer, can be under contract)
- Be in compliance with all federal requirements, including Home Infusion Therapy Conditions for Coverage.
- Have served a minimum of three patients. If a home infusion therapy supplier is in a rural area as defined by CMS, it should have served at least two patients. ACHC does not require an active patient for survey.
  - The three patients have to have been served in the home, not in an ambulatory care clinic.
- Clearly define the services it provides directly or under contract.
- Submit all required documents and fees to ACHC within specified time frames.
A patient is not required to be homebound to be eligible for the home infusion therapy benefit.

A patient can be homebound and under a Home Health (HH) plan of care, and require home infusion therapy services. In this case, the patient can receive both HH services as well as HIT.

In addition, the home health agency (HHA) and the home infusion therapy supplier may be the same entity in cases where the HHA is approved as a home infusion therapy supplier.
HOME INFUSION THERAPY BENEFIT VS. HOME HEALTH BENEFIT

- If a patient receiving home infusion therapy is also under a HH POC and received a visit that is unrelated to home infusion therapy, payment would be covered by the home health benefit and billed on the HH claim.

- If the HHA is the qualified home infusion therapy supplier and conducts a home visit solely for services related to the administration of the home infusion drug, the HHA would submit a home infusion therapy services claim under the home infusion therapy benefit.

- If a home visit includes provision of both HH and home infusion therapy services (i.e., separate services), the HHA would submit claims under the home health benefit and the home infusion therapy benefits. However, in this case, the HHA must separate the time spent providing the HH and home infusion therapy services.
HIT REIMBURSEMENT

- Home infusion will be a separate payment for professional services rendered.
- Payment will be made for each infusion drug administration calendar day.
  - Bundled payment for home infusion therapy services- only made when a skilled professional is in the home on the day of the drug administration.
- Based on 3 home infusion payment categories, with the associated J-codes (which describe the drugs covered under the benefit).
HIT REIMBURSEMENT

- Category 1: Anti-Infective, Cardiovascular, Pain, Other.
- Category 2: Subcutaneous Immune Globulin and not otherwise classified.
- Category 3: Oncology (considered the highest paying group).
- Users of multiple categories are grouped with the higher category.
## HIT REIMBURSEMENT

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>96365</td>
<td>Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy &amp; other highly complex drug or highly complex biologic agent administration) – up to one hour</td>
<td>1</td>
</tr>
<tr>
<td>96366</td>
<td>Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy &amp; other highly complex drug or highly complex biologic agent administration) – each additional hour</td>
<td>4</td>
</tr>
<tr>
<td><strong>Category 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>96369</td>
<td>Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy &amp; other highly complex drug or highly complex biologic agent administration) – up to one hour</td>
<td>1</td>
</tr>
<tr>
<td>96370</td>
<td>Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (excludes chemotherapy &amp; other highly complex drug or highly complex biologic agent administration) – each additional hour</td>
<td>4</td>
</tr>
<tr>
<td><strong>Category 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>96413</td>
<td>Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration – up to one hour</td>
<td>1</td>
</tr>
<tr>
<td>96415</td>
<td>Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration – each additional hour</td>
<td>4</td>
</tr>
</tbody>
</table>

*Payment Categories – CPT Codes

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[Logo: ACHC Educational Resources]
HIT REIMBURSEMENT

- The 3 payments categories are further broken down into a higher payment for the initial visit and lower payments for the subsequent visits.

- For a patient visit to be considered new again a gap of at least 60 days is required for another “first visit” to be billed (i.e., the patient must have been discharged from home infusion therapy for at least 60 days).

- Each category payment amount will be in accordance with the six CPT infusion codes described under the Physician Fee Schedule and equal to five hours of infusion.
# HIT REIMBURSEMENT

## TABLE 32: 5-hour Payment Amounts Reflecting Payment Rates for First and Subsequent Visits

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>2020 Proposed PFS Amounts</th>
<th>5-hour Payment – First Visit</th>
<th>5-hour Payment – Subsequent Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>96365</td>
<td>Ther/proph/diag IV inf 1 hr</td>
<td>$71.45</td>
<td>$255.25</td>
<td>$153.54</td>
</tr>
<tr>
<td>96366</td>
<td>Ther/proph/diag IV inf add hr</td>
<td>$22.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96369</td>
<td>Sub Q Ther inf up to 1 hr</td>
<td>$161.32</td>
<td>$357.44</td>
<td>$215.00</td>
</tr>
<tr>
<td>96370</td>
<td>Sub Q Ther inf add hour</td>
<td>$15.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>96413</td>
<td>Chemo IV inf 1 hr</td>
<td>$141.47</td>
<td>$422.70</td>
<td>$254.26</td>
</tr>
<tr>
<td>96415</td>
<td>Chemo IV inf add hr</td>
<td>$30.68</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note rates are adjusted by geographic area*
# HIT REIMBURSEMENT

<table>
<thead>
<tr>
<th>J-Code</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0133</td>
<td>Injection, acyclovir, 5 mg</td>
</tr>
<tr>
<td>J0285</td>
<td>Injection, amphotericin b, 50 mg</td>
</tr>
<tr>
<td>J0287</td>
<td>Injection, amphotericin b lipid complex, 10 mg</td>
</tr>
<tr>
<td>J0288</td>
<td>Injection, amphotericin b cholesteryl sulfate complex, 10 mg</td>
</tr>
<tr>
<td>J0289</td>
<td>Injection, amphotericin b liposome, 10 mg</td>
</tr>
<tr>
<td>J0895</td>
<td>Injection, deferoxamine mesylate, 500 mg</td>
</tr>
<tr>
<td>J1170</td>
<td>Injection, hydromorphone, up to 4 mg</td>
</tr>
<tr>
<td>J1250</td>
<td>Injection, dobutamine hydrochloride, per 250 mg</td>
</tr>
<tr>
<td>J1265</td>
<td>Injection, dopamine hcl, 40 mg</td>
</tr>
<tr>
<td>J1325</td>
<td>Injection, epoprostenol, 0.5 mg</td>
</tr>
<tr>
<td>J1455</td>
<td>Injection, foscarnet sodium, per 1000 mg</td>
</tr>
<tr>
<td>J1457</td>
<td>Injection, gallium nitrate, 1 mg</td>
</tr>
<tr>
<td>J1570</td>
<td>Injection, ganciclovir sodium, 500 mg</td>
</tr>
<tr>
<td>J2175</td>
<td>Injection, meperidine hydrochloride, per 100 mg</td>
</tr>
<tr>
<td>J2260</td>
<td>Injection, milrinone lactate, 5 mg</td>
</tr>
<tr>
<td>J2270</td>
<td>Injection, morphine sulfate, up to 10 mg</td>
</tr>
<tr>
<td>J2274</td>
<td>Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg</td>
</tr>
<tr>
<td>J3010</td>
<td>Injection, fentanyl citrate, 0.1 mg</td>
</tr>
<tr>
<td>J3285</td>
<td>Injection, treprostinil, 1 mg</td>
</tr>
</tbody>
</table>

*Infusion Drug
J-Codes- Cat 1
# HIT REIMBURSEMENT

## Category 2

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1555 JB*</td>
<td>Injection, immune globulin (cuvitru), 100 mg</td>
</tr>
<tr>
<td>J1561 JB*</td>
<td>Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (for example, liquid), 500 mg</td>
</tr>
<tr>
<td>J1562 JB*</td>
<td>Injection, immune globulin (vivaglobin), 100 mg</td>
</tr>
<tr>
<td>J1569 JB*</td>
<td>Injection, immune globulin (gammagard liquid), non-lyophilized, (for example, liquid), 500 mg</td>
</tr>
<tr>
<td>J1575 JB*</td>
<td>Injection, immune globulin/hyaluronidase (hyqvia), 100 mg immune globulin</td>
</tr>
</tbody>
</table>

## Category 3

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9000</td>
<td>Injection, doxorubicin hydrochloride, 10 mg</td>
</tr>
<tr>
<td>J9030</td>
<td>Injection, blinatumomab, 1 microgram</td>
</tr>
<tr>
<td>J9040</td>
<td>Injection, bleomycin sulfate, 15 units</td>
</tr>
<tr>
<td>J9065</td>
<td>Injection, cladribine, per 1 mg</td>
</tr>
<tr>
<td>J9100</td>
<td>Injection, cytarabine, 100 mg</td>
</tr>
<tr>
<td>J9190</td>
<td>Injection, fluorouracil, 500 mg</td>
</tr>
<tr>
<td>J9360</td>
<td>Injection, vinblastine sulfate, 1 mg</td>
</tr>
<tr>
<td>J9370</td>
<td>Injection, vincristine sulfate, 1 mg</td>
</tr>
</tbody>
</table>

*Infusion Drug J-Codes- Cat 2 & 3
PA YMENT FOR HIT SERVICES

- The single payment amount is limited so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day.
- In the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category will be made.
- In the event that multiple visits occur on the same date of service, suppliers must only bill for one visit and should report the highest paying visit with the applicable drug. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.
HIT BILLING PROCESS

- Providers will submit a single HCPCS G-code associated with the payment categories for the professional services furnished in the patient’s home and on an infusion drug administration calendar day.
- The CPT codes in Table 32 were used by CMS to determine the payment amounts for the home infusion therapy services.
- The claim will include a G-code, in line item detail, for each infusion drug administration calendar day, and the claim should include the length of time, in 15-minute increments, for which the professional services were furnished.
HIT BILLING PROCESS

- Home infusion therapy services payment is contingent upon a home infusion drug J-code being billed by the DME.
- Suppliers must ensure the appropriate drug associated with the visit was billed with the visit no more than 30 days prior to the visit.
HIT BILLING PROCESS

- **G-codes for billing:**
  - **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 (Short descriptor: Adm of infusion drug in home)
  - **G0069:** Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual’s home, each 15 minutes (Short descriptor: Adm of immune drug in home)
  - **G0070:** Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual’s home, each 15 minutes (Short descriptor: Adm of chemo drug in home)
HIT BILLING PROCESS

- Billing process for Qualified home infusion therapy suppliers, OTHER THAN AN HHA:
  - HIT claims are submitted on the 837p/CMS-1500 professional to the A/B Medicare Administrative Contractors (MACs).
  - DME suppliers, also enrolled as qualified HIT suppliers, would need to submit one claim for the DME, supplies, and drug on the 837p/CMS-1500 professional to the DME MAC and a separate 837p/CMS-1500 for the home infusion therapy professional services to the A/B MAC.
  - CMS states they are considering creating a “home infusion therapy supplier” type on the 855B enrollment form, but in the meantime, providers can enroll using the “other” option on the 855.
HOME HEALTH AGENCY BILLING PROCESS

- HHA do not need to apply for a Medicare Part B provider number.
- HIT Claims can be billed through the HHA current Home Health Medicare number.
- Claims are billed directly through Part B using the 34x TOB.
- Claims can be keyed directly into DDE.
RESOURCES

- **On Customer Central cc.achc.org**
  - Items Needed for Survey
  - HIT Desk Review Reference Guide
  - Crosswalk-Infusion Nursing to HIT
  - Crosswalk-Private Duty Nursing to HIT
  - HIT Survey Checklist-Personnel Files
  - HIT Preliminary Evidence Report
  - Separation of Services
  - Evidence Chart-HIT
  - ACHC Exit Packet-Completing the Plan of Correction
  - Clinical Documentation Expectations for Infusion Therapy

- “Did You Know?” Newsletter
  - Sign up at [https://www.achc.org/e-news-signup.html](https://www.achc.org/e-news-signup.html)
HIT WORKBOOK (COMING SOON)

- **Essential Components**
  - Each ACHC standard contains “Essential Components” that indicate what should be readily identifiable in policies and procedures, personnel records, medical records, etc.
  - Each section also contains audit tools, sample policies and procedures, templates, and helpful hints.

- **Other Tools**
  - Each section contains a compliance checklist and a self-assessment tool to further guide the preparation process.

- **Section Index**
  - Quickly locate important information for successfully completing the ACHC accreditation process.
QUESTIONS?

Imark Billing:
labarta@imarkbilling.com

ACHC Accreditation:
customersupport@achc.org
THANK YOU