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Monoclonal Antibodies for Home Health Agencies

Speakers

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Why HHA Should Know About mAbs

- In November, 2020, the FDA approved two emergency use authorizations for Monoclonal Antibody (mAb) Treatment for high-risk COVID-19 positive patients with mild or moderate symptoms.
- Medicare immunizers, including home health agencies, are eligible to administer and be reimbursed for this treatment under Medicare Part B. (No HIT Supplier credentials required)
- Target populations of eligible mAb treatment are the residents of Skilled Nursing Facilities and Assisted Living Facilities.

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Why HHA Should Know About mAbs

- In late December, the Ohio SPEED initiative distributed allocations to SNF/ALs. However, many facility operators are struggling to staff the Registered Nurse to monitor and administer the infusions.
- The Ohio SPEED initiative has requested a list of home health agencies who would be interested in administering this treatment in long term care settings.

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Reimbursement for mAbs

- Reimbursement Rate: $286.84
- LTC pharmacy Dispensing/Compounding: ~$140
- Excluded from SNF Consolidated billing
- Administration Time: 1 hour observation, 16-60 minutes administration
- Medicare advantage patients billed directly to Medicare
- Commercial/Medicaid billed to insurance
- No cost-sharing
- Roster billing available for clinics, also UB-04

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Billing for mAbs

Type of Bill	341- Home Health Part B
Revenue Code	0771
HCPCS Code	For Eli Lilly (bamlanivimab), M0239. For Regeneron (casirivi and imdevi), M0243
Required Condition Codes	A6- 100% payment 78- New Coverage for Medicare Advantage (bill for Medicare Advantage recipients only) 90/91- For dates of service after February 1, 2021
Diagnosis Codes	Z23- Encounter for immunization U071
Reimbursement for Ohio	$286.84

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Place of Service

Skilled Nursing Facility
Assisted Living Facility
Outpatient infusion clinics at hospital locations

While mAbs is permissible to administer in the home, we do not recommend this as an administration site.

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Documentation Requirements

- CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service. This includes documentation that supports that the terms of the applicable EUA are met, including that it is being used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for a patient that is at high risk for progressing to severe COVID-19 and/or hospitalization.
- The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.

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Resources

- Home Health Agencies: CMS Flexibilities to Fight COVID-19
  https://www.cms.gov/files/document/covid-home-health-agencies.pdf
- CMS SNF Enforcement Discretion Related to Certain Pharmacy Billing
  https://www.cms.gov/medicare/covid-19/snf-enforcement-discretion-relating-certain-pharmacy-billing
- CMS Monoclonal Antibody COVID-19 Infusion
  https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
- CMS COVID-19 Vaccines and Monoclonal Antibodies
  https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

Monoclonal Antibody Infusions for SARS-CoV-2

Rob Leffler, R.Ph.
February 2021

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Monoclonal Antibodies

- Monoclonal antibodies are proteins that are made in the lab that mimic the immune system's response to harmful antigens (like viruses)
- FDA has provided emergency authorization for two antibody treatments for SARS-CoV-2
  - Bamlanivimab (Lilly)
  - Casirivimab/imdevimab (Regeneron)

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Monoclonal Antibody Indication

- Indication: for outpatients with mild or moderate COVID-19 (positive test via viral testing) and are at significant risk of disease progression or hospitalization within 10 days of symptom onset (preferably within the first 3 days) AND
  one of the following:

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COVID-19 Mild to Moderate symptoms

- Fever 99 or greater
- New cough
- Sore throat
- Malaise
- Headaches
- Muscle pain or aches
- GI Symptoms
- SOB with exertion
- Loss of Taste or Smell

Antibody Therapy Contraindications

- Hospitalized patients
- Patients that require oxygen to be initiated or increased due to COVID-19
- Patients who are on hospice or hospice eligible or had a hospice/palliative care consult within 6 months

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Antibody Therapy Dosing and Administration

- Single dose via peripheral line over at least 16 minutes in Normal Saline depending on therapy
  - Administered via pump or by gravity
  - Flush line to ensure administration of entire dose
- No dose adjustments necessary/indicated for:
  - Elderly
  - Renal impairment
  - Hepatic impairment
- Vital signs should be monitored during infusion administration and post infusion for 1 hour

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Potential Adverse Reactions

- Hypersensitivity or infusion related reactions
  - Hypersensitivity could progress to anaphylactic reactions
    - Immediately discontinue administration and provide appropriate medications and/or supportive care
    - Infusion related reactions:

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Serious Event Reporting

- Any medication errors or serious adverse events must be reported on an FDA MedWatch Form within 7 days of the onset of the event by the prescriber or designee.
- Serious Adverse Events are:
  - Death
  - Life threatening events
  - Hospitalization
  - Persistent or significant incapacity
  - Congenital anomaly/birth defect
  - Medical or surgical intervention to prevent death, life-threatening event, hospitalization, disability or congenital anomaly.

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Hypersensitivity Management

- Provide supplemental oxygen to keep O2 > 94%
- Vital Signs every 10 minutes
- Contact Physician
- Complete MedWatch Event Report

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Post infusion

- Monitor patient for one hour
- COVID-19 vaccination should be deferred for 90 days after monoclonal antibody treatment

Coverage

- Currently the drug is being provided for free and the preparation and administration is covered under Medicare B as a single payment
- When/If this changes to a product that is purchased by pharmacies
  - It will be reimbursed similar to current vaccine methodologies

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Antibodies in the News

- McKnight's – "New 'weapon in our arsenal' : Antibody drug cuts COVID risk by 80 percent in LTC residents" – January 22, 2021
  - Phase 3 trial
  - Lilly is pursuing expanded EUA to prevention in SNF and ALF
- Wall Street Journal – "Regeneron Antibody Drug Temporarily Protects Against Covid-19, Preliminary Data Show"
  - Complete trial data is expected early 2nd quarter
  - Discussing the possibility of authorizing as a temporary vaccine
  - Expected to provide protection for at least one month

Thank you!

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