Highlights from the IG Living Teleconference, May 19, 2016

Topic: Transitioning to Medicare: What Patients Treated with Immune Globulin Need to Know

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This teleconference was an open question-and-answer session focusing on immune globulin therapy and reimbursement. Following is a summary of the questions and answers discussed.

General Medicare Information

The www.medicare.gov site has a lot of very helpful information on getting started with Medicare, including general coverage information, premiums and tools to help individuals select the right plan for them.

A helpful resource on the site is a booklet titled "Medicare and You," which is published every year and provides basic information and updates to Medicare. It is usually sent via mail. New Medicare recipients should receive it approximately three months before the month of their 65th birthday.

Those without Internet access can call Medicare at (800) MEDICARE (633-4227).

Enrolling in Medicare

The seven-month enrollment period begins three months before an individual turns 65. If individuals do not enroll during that seven-month period, they will be assessed some penalties for late enrollment.

Medicare Premiums

Premiums, deductibles, co-pays and other costs change annually. Premiums for 2016 are:

- Part A: Most people receive Part A costs without a premium. However, for those who have to buy Part A coverage, the premium for 2014 may be up to $411 per month. Part A generally covers hospital services, home nursing services (for homebound patients), skilled nursing facility costs (up to 100 days) and hospice care. Part A typically covers 100 percent of covered costs.

- Part B: Premiums vary based on income and range from $121.80 to $389.80 per month. Part B generally covers physician office visits, durable medical equipment, ambulance services and some outpatient services (e.g., IVIG in an outpatient infusion center). The Part B deductible for 2016 is $166. Part B typically covers 80 percent of charges. A Medigap or supplemental policy will cover the remaining 20 percent. A Medigap/supplemental plan will not cover anything that is not covered by Medicare.

- Part D: Premiums vary by the plan selected and may range from $0 to $80. Deductibles, co-pays and co-insurance also vary by the plan selected. Deductibles, co-pays, and co-insurance for a standard Part D plan are as follows for 2016:
    - Initial Deductible: $360
    - Initial Coverage Limit: $3,310 (patient portion is 25 percent)
    - Out-of-Pocket Threshold: $4,850
    - Coverage Gap (doughnut hole): Begins once a person has reached his or her Medicare Part D plan's initial coverage limit ($3,310 in 2016) and ends when that person spends a total of $4,850 in 2016.
      In 2016, Part D enrollees will continue to receive a 55 percent discount on the total cost of their brand-name drugs while in the doughnut hole. The 50 percent discount paid by the brand-name drug manufacturer will still apply to getting out of the doughnut hole; however, the additional 5 percent paid by the Medicare Part D plan will not count toward true out-of-pocket costs. Enrollees will pay a maximum 58 percent co-pay on generic drugs while in the coverage gap.
    - Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: Will increase to greater of 5 percent or $2.95 for generic or preferred drug that is a multi-source drug and the greater of 5 percent or $7.40 for all other drugs in 2016.
    - Maximum Co-Payments Below the Out-of-Pocket Threshold for Certain Low-Income Full-Subsidy-Eligible Enrollees: Will increase to $2.95 for a generic or preferred drug that is a multi-source drug and $7.40 for all other drugs in 2016.

- Medicare Advantage: These plans are like a traditional HMO/PPO. Many plans don't have a premium but will have co-pays/deductibles and co-insurance. If a Medicare Advantage plan is selected, an individual does not have traditional Medicare. This is the equivalent of "selling" the Medicare benefit to the insurance company that manages the HMO/PPO. They receive a monthly payment from Medicare to manage your medical expenses.

Information Specific to Immune Globulin (IG)

IG is covered when an individual transitions to Medicare; however, coverage varies by diagnosis and the location of the infusion.

- Immune Deficiency Diagnosis
    - Home Infusion
        - Part B:
            - Both intravenous IG (IVIG) and traditional subcutaneous IG (SCIG) are covered at home under Medicare Part B for 14 specific diagnosis codes, which reflect a small subset of primary immune deficiency diagnoses. Nursing is only covered if an individual is certified as homebound and must be provided by a Medicare-certified nursing agency. IVIG is covered under a specific IVIG benefit. Reimbursement for IVIG is at or below the cost to acquire the drug; plus, there is no coverage for supplies. SCIG is covered under the durable medical equipment benefit, so the drug is reimbursed because of the need for a pump to administer the drug. Reimbursement for SCIG is at a different rate and covers the cost of the drug for the home infusion provider. In addition, there is a payment for the pump and supplies. If a person is receiving IVIG for one of the 14 diagnosis codes and is about to turn 65, the home infusion provider may begin discussing a possible transition to SCIG. If an individual and his or her physician determines SCIG is not an option, the home infusion provider may work with that person and the physician to find an alternate site of service once transitioned to Medicare.

- HyQvia is the newest SCIG therapy, and typically a "ramp-up" is required to get to a final maintenance dose. The ramp-up doses are not covered in the home by Medicare Part B, and in some cases (Noridian), they are not covered in the hospital outpatient infusion suite. Once the maintenance dose is achieved, HyQvia is covered when administered with a programmable pump that is sent from the pharmacy in a locked mode. Supplies and pumps are covered. Nursing is not covered. Ramp-up doses may be available under Hello HyQvia, a free product trial program provided by HyQvia's manufacturer, Baxalta.

- Part B does not have a prior authorization process. Clinical information must support the diagnosis listed, as Medicare may review clinical information upon claims review.

➢ Part D: IVIG, traditional SCIG and HyQvia (including ramp-up doses) for other immune deficiency diagnoses may be covered at home under Part D. Prior authorization is required, and there is no coverage for nursing and supplies.

- Hospital Outpatient Infusion Suite or Physician Office

➢ IVIG is covered under the Part B benefit for a broader group of diagnosis codes and includes coverage for the drug, supplies and nursing. Coverage is based on the local coverage determination (LCD) for the intermediary in an individual's Medicare region. Reimbursement is still low, and some hospital infusion centers or physician offices may discuss transitioning to SCIG if an individual has one of the 14 diagnosis codes covered under Part B. Prior authorization is not required, but medical necessity may be reviewed during the claims submission process. If an individual has a different diagnosis such as selective antibody deficiency, his or her IVIG may be covered at home under the Medicare Part D benefit. There is no coverage for nursing and supplies under Part D, and most Part D plans require prior authorization. There may be coverage for nursing and supplies with a Medicare Advantage plan.

- Medicare Demonstration project

➢ This project is limited to 4,000 participants with one of the 14 diagnoses covered under Part B. It provides a small payment for nursing and supplies, but it does not address the low reimbursement for the drug. It applies to IVIG only.

➢ Approval for the demonstration project does not consider whether or not an individual has one of the 14 covered diagnosis codes, so just getting approved for the demonstration project does not ensure acceptance by a home infusion provider.

- Non-Immune Deficiency Diagnoses
    - Home Infusion
        - May be covered under the Part D benefit. There is no coverage for nursing or supplies under Part D, but there may be coverage with a Medicare Advantage plan. It requires prior authorization. Some diagnoses limit coverage for one course of therapy at a time (e.g., myasthenia gravis). The Medicare Modernization Act of 2003 limits coverage to a diagnosis with an U.S. Food and Drug Administration indication and/or positive reference in one of two recognized compendia (DrugDex or AHFS DI). Some rare diagnoses are difficult to authorize (e.g., autonomic neuropathy, Sjogren's syndrome) due to lack of reference in compendia.
    - Hospital Infusion Suite or Doctor Office
        - This coverage is the same as with home infusion with coverage under Part B. It is very important the prescriber and provider understand the current LCD as it relates to an individual's diagnosis. All clinical documentation should support the diagnosis to avoid payment denial during claims review.

How the Affordable Care Act Impacts Medicare

- Medicare is not part of the Health Insurance Marketplace, so individuals don't need to enroll via the exchange marketplace. All enrollment should be with Medicare and Medicare plans.

- Some preventive services are now covered at lower costs (e.g., wellness visits, mammograms, colonoscopies).

- Manufacturers are assisting with coverage during the doughnut hole for brand-name drugs. Manufacturers assist with 50 percent of coverage for brand-name drugs in the doughnut hole. This coverage amount increases each year, and the doughnut hole will be closed by 2020.

How to Be Prepared for the Transition to Medicare

- Individuals should begin discussing their options with their current providers of IG several months before transitioning to Medicare. They can work with their providers and physicians to determine the best way for them to continue care.
- If individuals can transition to SCIG or HyQvia, they should try to make the transition before their Medicare becomes effective so they don't have a break in care.

- Individuals should obtain copies of diagnostic tests, physician visits, labs, etc., which help support their diagnosis. These are necessary for prior authorization under Part D, and may be required to support claims payment under Part B.
- Individuals should know the LCD for their diagnosis and their Medicare region. If they don't meet the criteria, they can work with their providers to determine how they might appeal a denial or negative coverage decision. More information about this can be found at http://www.cms.gov/medicare-coverage-database/indexes/lcd-state-index.aspx?bc=AgAAAAAAAAAAAA%3D%3D&