Highlights from the IG Living Teleconference, December 6, 2018

Topic: How Medicare Covers Immune Globulin for Primary Immunodeficiency Diseases and Chronic Inflammatory Demyelinating Neuropathy

[This is an edited version of a live teleconference presentation.]

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I want to go over some terminology that I might use in this conference:

- PA stands for prior authorization.
- Fee-for-service refers to traditional Medicare.
- Medicare is basically broken up into two sections: fee-for-service (traditional) Medicare and the Advantage plans (also known as Part C).
- Supplemental (Medigap) plans are what you can purchase in addition to Medicare.
- The doughnut hole is also known as coverage gap.

Medicare and Primary Immunodeficiency (PI).

Under Medicare Part B (traditional), IVIG is covered 80 percent in the clinical setting for certain PI diagnoses. The other 20 percent needs to be covered by a supplement (or Medigap) plan. Medicare Part B will also cover IVIG in the home if a person is signed up for the demonstration project. Under the demonstration project, there are 15 different diagnoses of PI that are covered for IVIG in the home, as well as nursing and supplies that are covered within a bundled payment. However, if the diagnosis is not one of those 15, a person can qualify under Part D. So, PI is covered for either B or D, not both, and it is dependent on the location of the infusion and the diagnosis code.

Under Part B, IVIG is covered in the hospital or home. If the diagnosis is not covered under Part B, it can be covered under Part D. If a person has an Advantage plan, then traditional Medicare, Medigap and Part D are rolled into that Advantage plan. The Advantage plan takes the place of traditional (fee-for-service) Medicare. And, that is more like a traditional commercial plan. If a person signs up for an Advantage plan, premiums are paid to that plan either by the government or the insured. Advantage plans have to cover at least what Medicare covers for all diagnoses. So, if Medicare covers a diagnosis under Part B, the Advantage plan has to cover under the medical benefit. If that's not the case, then the Advantage plans can choose how they cover that benefit. Advantage plans are an advantage for all diagnoses for those under age 65 in the event a person cannot get a supplemental plan. Supplemental plans are not a guarantee issue, so if a person is under age 65 and not in a state where there is guaranteed-issue for Medigap, that person might be liable for 20 percent of the cost of the infusion, unless that person has an Advantage plan. With an Advantage plan, there are still deductibles, copays and out-of-pocket expenses, but there is also an annual maximum out-of-pocket cap. So even though a person will be paying out of pocket, he or she wouldn't be paying the extra 20 percent for the entire year because there is an out-of-pocket maximum that Part B does not have.

For subcutaneous IG (SCIG), it is different. SCIG is covered under Part B for PI under the durable medical equipment benefit at 80 percent for 15 diagnoses. That's because SCIG requires the use of a pump to infuse. And, again, this is only for PI. For the extra 20 percent coverage, a supplemental or Medigap plan is needed. If a person doesn't have one of those 15 diagnoses, he or she can access coverage under the drug plan, Part D. So, it's one or the other, not both. Like IVIG, a person can also have an Advantage plan. If a person's diagnosis is covered under Part B, the diagnosis will be covered under the Advantage plan. If not, a person can still get coverage under the drug plan. The difference with the drug plan is it has formularies. This means a person may have to use a certain brand of drug, and he or she may have to get prior authorization. Medicare does not require prior authorization, but Advantage and drug plans do.

Many people asked: "How do I get authorization for Medicare?" Medicare does not require prior authorization. Instead, it has coverage determinations (diagnostic criteria). Medicare audits files, so a person's doctor and specialty pharmacy are required to have records and charts to show that person qualifies for treatment. If Medicare decides to audit a person's chart and it doesn't find the proper diagnostic criteria, Medicare can take its money back. However, even though a person may be able to get coverage quickly and easily because there is no prior authorization required, the specialty pharmacy may require that person's doctor to have all the appropriate information in his or her chart before starting treatment. This is because the specialty pharmacy is the one that will lose the money if the chart is audited and is found it doesn't meet the diagnostic criteria. If the money is reclaimed, it takes years of appeals to get that settled, so that's why specialty pharmacies are a little more careful when starting Medicare patients on IG treatment.

Medicare and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Now, we will move on to Medicare and CIDP. A lot of this is the same information. IVIG coverage for CIDP is the same as for PI. The difference for CIDP is a person can use the same diagnosis and receive IVIG in the home under Part D. However, there will be more out-of-pocket expenses (deductibles and copays) and the doughnut hole will have to be met. That means a certain dollar amount has to be paid under Part D to meet the coverage gap after which is known as the catastrophic level. Up until the catastrophic level is reached, a person is supposed to pay 100 percent, but because of the Affordable Care Act, a person really pays about 45 percent and the manufacturer picks up the rest.

With Part D, the catastrophic level is not like commercial insurance. Under Part D, there is still a 5 percent coinsurance fee, whereas with a commercial plan, a person is covered 100 percent. There is no cap after which a person is covered 100 percent; there is still a 5 percent coinsurance fee. So, a person should keep that in mind when deciding which to choose.

To summarize, under Part B, there is 80 percent coverage and the supplemental plan pays the remaining 20 percent. Under Part D, it varies depending on the plan. The doughnut hole has to be reached and a 5 percent coinsurance fee has to be paid once the catastrophic level is reached. However, a person can receive treatment in the home and treatment can be received from specialty pharmacies. And, sometimes, specialty pharmacies can assist with coinsurance fees.

Then, there is Part C for CIDP. Part C is the same as for PI. It covers IG infusions very much like commercial insurance in which there is a deductible, copay and maximum out-of-pocket. And, Part C plans can decide where they're going to cover treatment. A lot of commercial payers are actually pushing patients out of the hospital setting and into the home or outpatient clinics. So, Part C is essentially what a person had before Medicare.

SCIG is covered for CIDP under Part D. This means there is still the deductible, out-of-pocket expense, doughnut hole and catastrophic level. For Part D, there also is a very strange rule, and this is also true for PI. Part D plans are mandated to make sure a patient has access to a pump and supplies, but they don't necessarily have to pay for it. Part D plans sometimes will consider a bundled payment, and sometimes they let the specialty pharmacy decide how to manage that. So, it's not very clear on plans whether the pump and supplies are covered. A person needs to do a benefit investigation and ask some very pointed questions. The specialty pharmacy will help a person understand what is paid for and what isn't. So, if a person is considering SCIG infusions for CIDP, I would encourage him or her to work closely with the manufacturer and specialty pharmacy to know how much that person will be responsible for paying.

SCIG for CIDP under Part C (Advantage plans) can be covered. Very much like IVIG, Advantage plans can decide how to work that, and they will have maximum out-of-pockets, copays, coinsurance and deductibles. But there will be a set maximum after which the person is 100 percent covered.

Supplemental Plans and Financial Assistance

Many people asked for advice about obtaining a supplemental plan. Unfortunately, that's definitely something I can't give, because supplemental plans are managed at the state level. And, at the state level, there may be 20 different plans. My advice is to work with the manufacturer's program. Some manufacturers have insurance counseling. In addition, they can help with Part D plans. With Part D plans, especially, I would advise a patient to go to his or her specialty pharmacy (or retail pharmacy if taking other other drugs) and take a list of medications to see what's covered.

Keep in mind that manufacturer copay assistance is not allowed by the U.S. government because it considers that an inducement to go on treatment. So, if a person had copay assistance before turning Medicare age, he or she won't have it once on Medicare. The government does allow specialty pharmacies to help, and most specialty pharmacies have a financial assistance program. However, a person has to ask for it. Specialty pharmacies are not going to offer it to a patient because, again, it is considered an inducement, and they could get in trouble. Therefore, a person shouldn't get frustrated with a specialty pharmacy if it doesn't tell him or her about its financial assistance program. It's something a person has to express a need for and ask for. Once asked, a patient will have to provide financial information to see if he or she qualifies under the specialty pharmacy's formula.

Sometimes nonprofits have funding. There is not much assistance for PI, and I'm not sure how much is out there for CIDP, but there is occasionally some money. And, nonprofits will also help with premiums.

Low-income prescription assistance is a program that is not very well utilized. This is a government-funded program through which individuals get discounts on Part D premiums and a low fixed cost for prescriptions. The qualifications are around $17,000 per year for an individual. There are also certain things an individual can and can't own.

Disability with Medicare

Sometimes, people who have PI or CIDP and have gone undiagnosed for a long time might qualify for disability. Once a person receives disability, there is a two-year waiting period from the date of disability until he or she qualifies for Medicare. And, during those two years, a person will need other coverage. Keep that in mind when thinking about applying for disability.

Changes in Medicare

A lot of people asked about what changes were coming for Medicare. There is a demonstration project coming up that the current administration would like to try in which specialty pharmacies are reimbursed based on what other countries' pay. The government wants to put 50 percent of Medicare patients into this demonstration project. I'm not sure how that will go, but it's something to keep an eye on.

There was a slight increase in premiums for Medicare. There is was a good change for PI patients treated with SCIG. Starting Jan. 1, there will be an add-on fee for SCIG patients receiving treatment under Part B. This is only for PI because currently CIDP patients cannot get coverage under Part B. Under this, specialty pharmacies will be able to access a monthly payment for monitoring PI patients using SCIG via the Part B durable medical benefit. And, that's important because the 21st Century Cures Act dropped the rate of reimbursement for SCIG to match what IVIG therapy costs (average sales price plus 6), and that hurt specialty pharmacies' income levels.

Lastly, Medicare is continuing the IVIG demonstration project for PI patients that was scheduled to end this year while they look at the data and decide whether to continue it permanently.

Formularies

Different payers can have different formularies. There are a couple of very large payers that also have least-costly alternative policies or clinically equivalent medication in which they choose the cheapest of the IG products. IVIG and SCIG products are not all the same; they are all made differently. But, insurance companies consider them biologically equivalent, and they're trying to cut costs by limiting which brands are used. Fortunately, there are ways around that because not everybody responds the same to each product.

One way around this is a not-well-known coverage or medical policy that shows patients how to keep access to their current product, especially if they switch from one insurance company to another. For instance, Anthem and Aetna both have this policy, which states an exception can be made. Some of these policy exceptions include being already stable on a product or having tried a product that doesn't work.

Part D plans and Medicaid have a lot of formularies. And, they all have exceptions to those formularies because the manufacturers pay rebates. In fact, they have to have a formulary exception by which the doctor can request to use the product that he or she feels is best for the patient.

Cost Transparency

A person has the right to his or her information. The manufacturers and specialty pharmacies can be as transparent as they want. But, whatever the insurance will pay is what really affects a patient most. That is what determines the patient's out-of-pocket expense, copay or coinsurance.

If a person wants to know what a drug costs, Medicare has a website that lists the average sale price. But, as far as getting information that pertains to a particular patient, there are a few ways to go about that. Again, a person can go to the manufacturer and ask for help. The manufacturer can call the person's insurance company on his or her behalf. Or, a person can call his or her insurance company on his or her own behalf. When calling, this is the information needed:

- Diagnostic code (obtained from the doctor)
- J code to the product (obtained from the specialty pharmacy)
- National drug code (a 10- or 11-digit code located on the medication's box and bottle)
- Dose and frequency
- HCPCS supply code (obtained from the infusion provider)
- Procedure codes (obtained from the doctor or specialty pharmacy)
- Site-of-care code (if applicable, also obtained from the specialty pharmacy)

Once this information is obtained, the insurance company should be able to tell a person whether the drug is covered under the major medical or prescription benefit. Oftentimes, a person will be told the drug isn't covered, but it may be that the specialty pharmacy is just not covered. Patients should be sure to ask both about the medical benefit and the prescription benefit. Other things the insurance company should be able to provide are:

• deductible amount

• copay or coinsurance amount

• maximum out-of-pocket cost(Some companies are different. Some require the maximum. This year, it was $7,350. Next year, it is expected to go up to $7,900.)

• how much out-of-pocket expense has been met

• who is in network and who is not

Sometimes, it's possible to fill out a profile online with the insurance company to access the information electronically.

Enrolling in Medicare

People either age into Medicare or obtain Medicare due to a disability. The most important thing is to sign up when it's time. People have a three-month period before they turn 65 and a three-month period after, as well as the month they turn 65. I would encourage people to make those choices before then. If a person does not sign up for an eligible program, he or she will need a good reason such as already having coverage. If a person doesn't have a reason and needs to sign up the next year, he or she will be penalized — in some cases up to 10 percent per month for premiums, and it's a lifetime penalty.

However, should a person have coverage and not need Medicare at age 65, but then need it later for a reason such as losing a job, that person then has a qualifying event. At that point, the person has another option for opting into Medicare without a penalty. So, it's necessary to make the best decision for life rather than for just that time.

Medicare is very complicated. I encourage people to be wary of brokers because they often don't understand a person's disease state or medication. Brokers simply plug a disease code into a formulary to determine what is and isn't cover, which is not always the right way to figure things out. Brokers also make money off of those they sign up.

Traveling and SCIG

Is traveling feasible with SCIG? SCIG supplies are very easy to transport, but the big issue is when travel takes place. Shipments usually contain a 28- or 30-day supply, and a lot of insurance companies (Medicare, Medicaid and commercial) are only going to provide a maximum 30-day supply. So, if travel is right after a shipment and only lasts within that 30-day window, it's not a problem. If, however, the trip is for longer, it will take some planning. Sometimes, a person can work with the insurance company to pay premiums in advance to receive a one-time exemption. But, pharmacies can only ship to a United States address. Some specialty pharmacies can make arrangements when traveling throughout the U.S., but not outside the U.S. The key is to plan in advance.

As far as traveling requirements, I would read many of the IG Living articles that have been written on the subject.