Highlights from the IG Living Teleconference, January 26, 2017

Topic: How the 21st Century Cures Act Impacts Immune Globulin Reimbursement

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

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The 21st Century Cures Act was signed into law in December 2016 with an effective date of Jan. 1. The bill had very strong bipartisan support with Congress approving it 392 to 26 in the House and 56 to 4 in the Senate. The act had many provision. Some of the good key provisions are to:

- speed new medicine to market
- increase innovation
- provide 4.8 billion for research, including the cancer moonshot (to cure cancer) and the brain initiative (to figure out how the brain works)
- provide funding for the precision medicine initiative to tailor medicine to patient specific genomes
- provide an additional $1 billion to fight opioid crisis
- provide funding for mental health

Because the act's provisions come with a heavy price tag, Congress had to find ways to offset the costs, two of which affect reimbursement for immune globulin (IG) therapy infusions in the home setting. These sections, 5004 and 5012, are referred to the "pay portions" of the act.

Section 5004

Section 5004 changes reimbursement for IG effective Jan. 1, 2017. Specifically, it changes reimbursement for IG infused in the home from 95 percent of the first published average wholesale price to the average sales price plus 6 percent, less a 2 percent reduction of payment due to the federal sequestration required under the Budget Control Act of 2011. As legislated, applying sequestration of 2 percent to 80 percent of Medicare payment portions changes the actual reimbursement to ASP plus 4.3 percent (which is in line with how most Medicare Part B drugs are paid for). While this change had been recommended by the Office of the Inspector General for several years, until now, it had not made it into legislation likely to pass.

This change only impacts the 14 primary immune deficiency diagnoses (ICD10 codes):

D80.0	Hereditary hypogammaglobulinemia
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D83.0	CVID w/predominantly abnormality of B-cell numbers & function
D83.2	CVID w/autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D82.0	Wiskott Aldrich Syndrome
D81.0	Severe combined immunodeficiency with reticular dysgenesis
D81.1	Severe combined immunodeficiency w low T- and B-cell numbers
D81.2	Severe combined immunodeficiency w/ low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined Immunity Deficiency, unspecified

This section dramatically changes reimbursement, and in some cases, it makes reimbursement lower than the actual cost to buy.

Section 5012

Section 5012 adds reimbursement for services for drugs (except those on the self-administered drug list, e.g., Hizentra) for home infusion providers effective Jan. 1, 2021. The dollar value of the reimbursement is not yet defined. However, it is noted in the act that payment can't exceed the current payment paid to doctors for office administration.

Right now, under Medicare Part D, there is no coverage for supplies or nursing in the home, so patients oftentimes have to pay out of pocket or specialty pharmacies try to find other ways to offset the cost. When this section goes into effect, however, specialty pharmacies will be reimbursed for supplies and nursing covered under Medicare Parts B and D.

The Section 5004 and Section 5012 Gap

Unfortunately, there is a four-year gap between when reimbursement changed under section 5004 and when reimbursement is scheduled to be reinstated under section 5012. Patients, therefore, may be asked to switch to another IG product and/or to change to an infusion setting other than the home to make it affordable for specialty pharmacies to treat patients with IG.

Currently, the National Home Infusion Association, Immune Deficiency Foundation and American Academy of Allergy, Asthma and Immunology are lobbying to either get the effective date for Section 5012 moved up, or the effective date for Section 5004 delayed, to eliminate the gap. It is unknown whether they will be successful. However, it may be more likely that Section 5012's effective date gets moved up because it would generate more savings. While payments would still need to be made to home infusion providers, it would decrease hospital and doctor office charges, which are more expensive.