Research

Studies Show Improved Treatment Satisfaction with SCIG vs. IVIG

Two Phase II/III prospective clinical studies, one in North America and one in Europe, report improved treatment satisfaction with a new human 20% subcutaneous immune globulin (SCIG) versus prior intravenous immune globulin (IVIG) treatment. The studies compared the treatments using the Life Quality Index instrument after patients completed IVIG and again after SCIG 20% treatment. In the North American study, patients received three months of IVIG prior to receiving 12 months of SCIG 20% treatment, and reported improvements in LQI of 33.5 versus 36.5. And, patients in the European study received 12 months of treatment with SCIG 20% following a three-month treatment period with either IVIG or SCIG 20%, and reported LQI improvement of 34.5 versus 39.0. In addition, patients “reported improvement relative to the IVIG therapy period after treatment with SCIG 20% in the therapy setting LQI domain, improving from 17.5 to 20.0 in the North American study and from 18.0 to 21.0 in the European study,” according to lead study author Lisa Meckley, PhD, of Shire Pharmaceuticals, and coauthors.


Resources

CGD Connections Launched to Support the CGD Community

Horizon Pharma has partnered with people living with chronic granulomatous disease (CGD), their families, caregivers and healthcare professionals, as well as advocacy organizations, to create CGD Connections, an initiative by and for the rare genetic disease that weakens the immune system and can lead to repeated, severe infections.

CGD Connections is an online platform that provides disease and treatment information, offers tips for managing everyday life and fosters connection among the community across CGDConnections.com and the CGD Connections Facebook page. The site also links families to leading organizations, including the Immune Deficiency Foundation and its LivingWithCGD.org website, as well as the Jeffrey Modell Foundation.

“Having CGD can be scary and feel isolating,” says Randall G., who lives with CGD and participated in one of Horizon’s workgroups. “CGD Connections provides a place to connect with those who know what it’s like to have or care for someone who has CGD, and includes information to help on the typical days, as well as how to find strength to tackle the hard ones. Collaborating with other CGD families in the development of this initiative raised shared challenges and led to the creation of resources that we hope will inspire and provide support for those at every stage of their CGD journey.”

Researchers from VA Ann Arbor Health Care System, University of Michigan (U-M) Medical School and Penn State University have found that individuals with chronic health conditions who choose health insurance plans with a deductible spend hundreds or even thousands of dollars of their own money on their care, beyond what they spend to buy the insurance plan. The study analyzed data from 17,177 Americans under age 65 who were interviewed for the Medical Expenditure Panel Survey that showed just over 4,100 had a high-deductible health plan, and 44.5 percent had a chronic health condition, which made it more likely that health-related costs took up more than 10 percent of a chronically ill person’s total income. It also showed huge variations in the amount of out-of-pocket spending between patients who have the same condition, even for low-deductible plans. Yet, despite the out-of-pocket expenses, the study found few people with chronic illnesses said that costs or insurance coverage issues had gotten in the way of getting the care or prescriptions they needed.

Findings are based on data from 2011 through 2013, when many more employers started offering high-deductible plans and before individuals were able to buy their insurance on the HealthCare.gov marketplace. Since the launch of the marketplace, more than 90 percent of people shopping there have chosen high-deductible plans. “Increasingly, these plans have become woven into the fabric of health insurance in America, so it’s important to look at the impact of deductibles on people who need care on an ongoing basis,” said senior author Jeffrey Kullgren, MD, MS, MPH, a research scientist in the VA Ann Arbor Healthcare System and an assistant professor of general medicine at the U-M Medical School. “Not only on how they spend their money on care for their day in, day out health needs, but how that affects spending in the rest of their lives.”


Did You Know?

CSL Plasma has teamed with Wirecard North America to launch the first cash-back donor prepaid card, providing a one-time milestone reward and cash back for spending at local grocery stores and quick-service restaurants that is paid directly to the card. The cash-back option was introduced to support the platinum level loyalty tier of CSL Plasma’s new iGive Rewards Loyalty Program. “Our collaboration with Wirecard has allowed us to offer a new platinum level to iGive Rewards that offers more exclusivity and benefits to our valued donors,” said Robert Mitchell, CSL Plasma’s director of marketing and corporate communication. “With the personalized cash-back rewards prepaid card, platinum level donors receive additional points and other perks… The evolution of the iGive program and platinum rewards is another way that CSL Plasma is delivering on its promise to give back to the donors who give their time to make sure plasma is available to make lifesaving therapy for patients in need.”
Shire has published three special editions of the quarterly magazine *Just Like Me* for 2017: Living with PI, Living with PI (for kids) and Understanding Insurance. Debuted in 2012, *Just Like Me* is a resource for children diagnosed with primary immunodeficiency disease (PI) and their families to inform them about serious topics related to their disease state in a fun and friendly way. The quarterly magazine is broken up into kids and teen sections, and also includes an insert for adults. Patients can begin receiving the quarterly and special editions by enrolling in Shire’s MyIGSource program at [www.myigsource.com/enroll-primary-immunodeficiency-support-program](http://www.myigsource.com/enroll-primary-immunodeficiency-support-program).

**Resources**

### Three *Just Like Me* Special Editions Published for Children with PI

John G. Boyle, son of the Immune Deficiency Foundation’s (IDF) president and founder, Marcia Boyle, who previously announced her plan to retire, will serve as the foundation’s new president and chief executive officer. John Boyle brings a wide base of nonprofit management experience to the position, having held a number of executive positions with leading national nonprofit organizations throughout his career and currently serving as the vice president of external relations at IDF. He was instrumental in developing a number of new initiatives for IDF, including the IDF Walk for Primary Immunodeficiency (PI) that launched in 2013 and has grown to 12 cities across the U.S., raising in excess of $1 million to support IDF programs and resources.

“It is an honor to build upon Marcia’s legacy of leadership as IDF continues to work to meet the current needs of the PI community, and to prepare for the community’s future needs,” said Boyle. “It is both an exciting and a challenging time for the people we serve: There are new advancements in treatment options on the horizon, but also growing uncertainty in terms of healthcare policy and insurance limitations. We have an amazing team at IDF, and I am thrilled to continue to work alongside them each day to reach more members of the PI community and to further advance our advocacy, education and research initiatives.”

**Industry**

### John G. Boyle Named President and Chief Executive Officer of IDF

**Medicines**

### Shire Launches Pediatric Indication for HyQvia in Europe

Following the recent marketing authorization by the European Commission, Shire (previously Baxter) has launched a pediatric indication for HyQvia (human normal immune globulin 10%) in Europe to treat primary and certain secondary immunodeficiencies. Shire commercially introduced the new indication across the member states of Europe beginning with Germany, Netherlands, Ireland, Greece, Slovakia, Denmark, Sweden and Norway. “We are pleased to bring pediatric patients a new therapeutic option as we build on our broad immunoglobulin portfolio for patients with immune deficiencies,” said Ueli Frankhauser, head, global product strategy. “We intend to expand the availability of HyQvia to more patients in additional geographies, with the goal of reducing the treatment burden for patients worldwide.”

Research

Study Shows the Home-Based SCIG Therapy Setting Provides Higher Satisfaction Among Pediatric Patients

A study conducted in France that assessed quality of life and satisfaction regarding the route and place of administration of immune globulin (IG) replacement therapy treatment found that the home-based subcutaneous IG (SCIG) therapy setting provided higher satisfaction than the hospital-based intravenous IG (IVIG) setting among children. In the prospective, noninterventional cohort study, 44 children aged 5 years to 15 years who had been treated with IG for primary immunodeficiency disease (PI) for three or more months were followed over 12 months. Eighteen of the children were receiving hospital-based IVIG, two were receiving home-based IVIG and 24 were treated with home-based SCIG.

Quality of life was assessed with the child health questionnaire parent form (CHQ-PF), and satisfaction with treatment was measured with a life quality index (LQI) with three components: treatment interference, therapy-related problems and therapy settings. No difference was found on the CHQ-PF assessment. And, there was no difference between the LQI treatment interference and therapy-related problems components. However, the LQI therapy settings component was higher for home-based SCIG than for hospital-based IVIG. And, the LQI therapy settings component significantly improved in five patients who switched from IVIG to SCIG during follow-up when compared to patients who pursued the same regimen (either IVIG or SCIG).


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Autoimmune Corner

Medicines

FDA Approves Renflexis, Biosimilar to Remicade

The U.S. Food and Drug Administration has approved Renflexis (infliximab-abda, Samsung Bioepis), the second biosimilar to Remicade (infliximab, Janssen Biotech). Inflectra (infliximab-dyyb, Celltrion) was the first approved biosimilar. The tumor necrosis factor blocker is an intravenous infusion (100 mg) indicated for the same indications as Remicade: Crohn’s disease, ulcerative colitis, rheumatoid arthritis (in combination with methotrexate), ankylosing spondylitis, psoriatic arthritis and plaque psoriasis. The most common adverse reactions that occurred in fewer than 10 percent of patients in clinical trials are infections (e.g., upper respiratory infection, sinusitis and pharyngitis), infusion-related reactions, headache and abdominal pain, which are similar to those seen with Remicade. In addition, Renflexis also comes with the same boxed warning as Remicade concerning the increased risk of serious infections.

Guidelines

AHA Updates Kawasaki Disease Diagnosis and Management Guidelines

The American Heart Association (AHA) has made its first update to the diagnosis and management guidelines of Kawasaki disease issued in 2004. The revised guidelines integrate new findings on the epidemiology, genetics, pathogenesis and long-term outcomes of the disease. Specifically, the revisions fall into four categories:

Pathogenesis. The new guidelines propose there are three linked pathological processes: 1) necrotizing arteritis, which “destroys the arterial wall into the adventitia, causing aneurysms,” 2) subacute/chronic vasculitis, “characterized by an asynchronous infiltration of lymphocytes, plasma cells and eosinophils with fewer macrophages that begins in the first two weeks after fever onset but can continue for months to years in a small subset of patients and is closely linked to the third process” and 3) myofibroblastic proliferation, which involves a unique medial smooth muscle cell-derived myofibroblastic process that can cause progressive arterial stenosis.

Diagnosis. Because a prompt diagnosis is critical, the revised guidelines include an updated algorithm outlining supplemental information that may facilitate the diagnostic process in cases lacking complete classic clinical criteria.

Treatment. In addition to administering intravenous immune globulin (IVIG) as soon as possible within 10 days of fever onset, the revised guidelines recommend IVIG for children who present after the 10th day with “ongoing systemic inflammation as manifested by elevation of ESR [erythrocyte sedimentation rate] or CRP [C-reactive protein] (CRP >3.0 mg/dL) together with either persistent fever without other explanation or coronary artery aneurysms (luminal dimension Z score >2.5).” The revision also includes recommendations for additional therapies, including corticosteroids, infliximab and cyclosporine in patients who are IVIG-resistant, as well as detailed recommendations for management based on coronary artery involvement.

Risk classification. A new classification of coronary artery abnormalities is based on Z scores as follows, with certain caveats:

• No involvement: always <2
• Dilation only: 2 to <2.5, a decrease in Z score during follow-up ≥1
• Small aneurysm: ≥2.5 to <5
• Medium aneurysm: ≥5 to <10, and absolute dimension <8 mm
• Large or giant aneurysm: ≥10, or absolute dimension ≥8 mm

The authors note that important gaps in evidence remain, and “until the cause and pathogenesis are defined, an exact diagnostic test remains elusive, and acute treatment remains somewhat empirical.”

The full guideline can be downloaded at circ.ahajournals.org/content/early/2017/03/29/CIR.0000000000000484.

Medicines

FDA Grants Orphan Designation for Octagam 10% to Treat Dermatomyositis

The U.S. Food and Drug Administration has granted Octapharma USA orphan drug designation for Octagam (immune globulin intravenous [human] 10% liquid) for treatment of dermatomyositis. Orphan drug designation is given to drugs and biologics to treat rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect 200,000 or more people, but whose sales are not expected to recover the costs of research and development of the product.

Dermatomyositis is a rare acquired disorder characterized by chronic inflammatory and degenerative changes of the muscles and skin. Its main symptom is a skin rash accompanied or followed by progressive muscle weakness. The disease, which has an estimated incidence of 9.63 cases per million, is most common in children between ages 5 years and 15 years and adults in their late 40s and early 60s, but can occur at any age.


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