RISING HEALTHCARE COSTS: A Deeper Look Into Catastrophic Claims

by Stacy Borans, MD, Chief Medical Officer, Advanced Medical Strategies
It comes as no surprise to anyone that healthcare costs continue to rise. We are all aware of the common conditions that result in catastrophic claims: cancers, premature babies, spinal surgeries, end-stage renal disease, and diseases requiring transplants. The list is seemingly endless. This article’s focus is on overlooked conditions, their treatments and associated catastrophic claims costs (which often times are much higher than the aforementioned common conditions).

**Paroxysmal Nocturnal Hemoglobinuria**

Paroxysmal Nocturnal Hemoglobinuria (PNH) is a rare blood disorder. The disease is characterized by destruction of red blood cells (hemolytic anemia), blood clots (thrombosis), impaired bone marrow function, and a 3 to 5% risk of developing leukemia. PNH affects only 1-2 people per million of the population, striking mostly young adults. The median age at diagnosis is 35-40 years of age. PNH is very closely related to aplastic anemia and often evolves from that disease. The median survival for patients with this disease is approximately 10 years although many can live for much longer periods of time with only minor symptoms. The classic symptom is bright red blood in the urine (hemoglobinuria) although many patients notice their urine is a dark tea-color. Typically, hemoglobinuria will be most noticeable in the morning, and clear as the day progresses.

Treatment for this disorder will depend on the severity of the symptoms and the degree of marrow dysfunction. Allogenic bone marrow transplant had been the mainstay of treatment for many years – it is risky, fraught with complications, and most patients were unable to find a donor. This form of treatment is currently reserved for severe cases of PNH with aplastic anemia or those whose conditions transform to leukemia, both of which are life-threatening complications. Allogenic bone marrow transplant is very costly: 2011 Milliman reported billed costs for this are $800k.

In 2007, the FDA approved Soliris (eculizumab) for the treatment of PNH. This is currently the standard of care for therapy for this disorder. Soliris is a monoclonal antibody that ultimately stops the destruction of red blood cells and alleviates the symptoms of PNH. Soliris does not correct the underlying genetic defect responsible for PNH; it simply improves the symptoms, improves quality of life, and eliminates many of the complications of PNH. Hence, Soliris is a life-long therapy (unless the patient achieves spontaneous remission, which only occurs in 10% of cases).

Soliris is given via intravenous infusion. The current dosing schedule for PNH is: 600 mg weekly for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later; then 900 mg every 2 weeks thereafter. Soliris only comes in 300 mg vials. Average wholesale price (AWP) for the vial is $6,830. AWP for the first 4 weeks of treatment is $54,640; for subsequent doses, $20,490; for a full year of therapy, approximately $550,000. As a general guideline, I use 200% of AWP for assessing the reasonableness of a charge. Based on that, reasonable charges for a full year of Soliris therapy are $1.1M. However, actual costs could be significantly higher depending on the inflation of the drug. At 400% of AWP, one year of Soliris therapy would be 2.2M and it is not unusual to see that degree of drug inflation (or more).

**Atypical Hemolytic Uremic Syndrome**

Soliris is also used in the treatment of another disorder: atypical hemolytic uremic syndrome (aHUS). This is another rare disease that primarily affects kidney function. aHUS is characterized by three major features related to abnormal clotting; hemolytic anemia, thrombocytopenia (low platelets), and kidney failure. The disease mainly affects children and has an incidence of 1 in 500,000 per year. There is a clear distinction between hemolytic uremic syndrome and aHUS. Hemolytic uremic syndrome is caused by particular strains of the bacterium E.coli producing Shiga toxins while aHUS has a genetic component similar to the one in PNH. aHUS may become a chronic condition and patients may experience repeated attacks of the disorder. When children with Shiga toxin producing HUS recover from the life-threatening initial episode, they are likely to respond well to supportive treatment and to make a good recovery. Children with aHUS are much more likely to develop chronic serious complications. In the past, treatment required plasma exchange/plasma infusion and many patients still progressed to end-stage renal disease, prompting dialysis – the costs of which can exceed well over $400-$500k per year. Soliris has eliminated the need for plasma exchange/infusion and dialysis while also normalizing blood counts and preventing further clotting episodes.

So, let’s talk numbers. Solaris dosing for aHUS is: 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later; then 1200 mg every 2 weeks. Average wholesale price for the first 4 weeks of treatment is $81,960; AWP subsequent doses, $27,320; a full year of therapy is approximately $737,640. As noted previously, I use 200% of AWP for assessing the reasonableness of a charge. Based on that, reasonable charges for a full year of Soliris therapy for aHUS are...
approximately $1.5M. Should the drug inflation be closer to 400%, one full year of therapy approaches $3M. The outcomes for patients are significantly better with Soliris, but it does come at a very high price.

Cystic Fibrosis

Cystic fibrosis (CF) is another genetic childhood disorder that carries significant morbidity and mortality. Patients are often diagnosed as infants (6-8 months). The disorder’s main affected organ is the lungs. These patients produce thick, viscous secretions and respiratory failure is the main cause of death. CF is caused by a mutation in the gene for the protein CFTR (cystic fibrosis transmembrane conductance regulator). This protein is required to regulate the components of sweat, digestive fluids, and mucus. While most people have two working copies of the gene, in CF patients both copies of the gene are dysfunctional. Though there is no cure for CF many patients do live well into adulthood with current modalities. Treatment is often supportive, directed at limiting and treating the lung damage caused by the secretions and pulmonary infections. Lung transplantation is required when pulmonary function reaches critical deterioration. CF patients must have both lungs transplanted as both lungs are affected. Additionally, should there be infection/bacteria in one lung, that could affect a newly transplanted lung causing rapid failure of the organ. A pancreatic or liver transplant may be performed at the same time in order to alleviate liver disease and/or diabetes. 2011 Milliman reported billed charges for double lung transplant are $797,300; $289,400 for pancreas transplant; $577,100 for liver transplant. Should all three transplants be done, claims for that CF patient would easily approach $2M.

Unstable and end-stage CF patients are not the only ones who incur large claims. In 2012, the FDA approved Kalydeco (ivacaftor) as a drug designed to help improve the defect in the CFTR gene. One study observed lung function improvement at 2 weeks that was sustained through 48 weeks. The study also observed improvements in risk of pulmonary exacerbations, patient-reported respiratory symptoms, weight gain, and concentration of sweat chloride. Kalydeco is indicated for patients who are 6 years of age or older and who have the G551D mutation of the CF gene. It is not indicated for other mutations in the gene. The drug is oral and patients take one 150 mg tablet every twelve hours. Average wholesale price for a 30 day supply of the tablets is $30,724. Using my previous calculations, reasonable charges for one full year of therapy would be approximately $738k. Specialty pharmacies may be able to

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reduce costs to under 200% of AWP but these patients will still have high yearly charges. This is due both to the medication and complications that are seen with the disorder.

**Malignant Melanoma**

Finally, there is malignant melanoma. Patients usually present with skin lesions that have changed in size, color, contour, or configuration. The main cause of malignant melanoma is sun exposure. Most stages of melanoma have lower overall claims costs. Even at Stage III, patients are treated with Interferon alfa whose costs rarely exceed $50k for a full year of therapy. However, there are drug therapies available for advanced melanoma which have significantly raised claims costs for this disease. The first is Yervoy (ipilimumab) which was FDA approved in 2011. It is indicated for patients with either unresectable or metastatic melanoma. In a clinical trial, patients treated with Yervoy survived a median of 10 months (versus 6 months in patients treated with other therapies). Yervoy did not work for every patient in the trial and these patients had failed previous conventional therapies. The drug is dosed based on weight as follows: 3 mg/kg IV over 90 min. It is given every 21 days for a total of 4 doses. Assuming a standard weight of 75 kg, a typical Yervoy dose would be 225 mg. A single 200mg vial of Yervoy has an AWP of $29,678; the full course of treatment would be approximately $120k. Reasonable charges would be $240k for the Yervoy but could certainly be higher. There is only a single course of therapy for this drug. In addition to melanoma, Yervoy is undergoing clinical trials for the treatment of non-small cell lung cancer; small cell lung cancer; and metastatic hormone-refractory prostate cancer.
The other drug utilized in metastatic melanoma is Proleukin. It was FDA approved in 1998 but appears to be utilized much more in the past few years. Proleukin requires inpatient care for each course and has a complicated dosing regimen as follows: 600,000 U/kg IV every 8 hours (maximum 14 doses); following 9 days of rest, repeat for another 14 doses (maximum 28 doses per course, as tolerated). This constitutes one course of treatment. The patient can receive further courses of therapy as long as disease regression is documented. Although the average wholesale price of Proleukin is very reasonable at under $2,000 for 22 million IU, claims for each course often approach $300-$350k. Each course of therapy should be separated by a rest period of at least 7 weeks from the previous hospital discharge. A full year of therapy has the potential to exceed $2M.

Each new therapy developed is poised to take claims costs even higher. Claims that reached $5M were once considered to be rarities – in the not-too-distant future they will be commonplace. It’s a sad fact that good medicine does not come cheaply to those who are in desperate need of it.

Dr. Borans is the Chief Medical Officer and Founder of Advanced Medical Strategies (AMS). Advanced Medical Strategies was founded with the purpose of combining clinical expertise and experience with financial sensitivity and understanding to give clients high-level cost containment insight and guidance.

Dr. Borans has worked with Managing General Underwriters, Third Party Administrators, stop loss carriers and managed care plans to assess both clinical and financial questions on catastrophic claims. She has assisted in cost projection analysis for underwriting risk, reviewed medical necessity and experimental concerns as well as directed educational seminars for claims professionals. Dr. Borans is currently the outsourced medical director for several companies within the stop-loss industry.

In addition to her vast medical management experience on the payer side, Dr. Borans has overseen medical and quality management, appropriateness of care and peer review programs in over 50 hospitals spanning 7 states.