DC MEDICAID FEE FOR SERVICE DRUG UTILIZATION REVIEW (DUR)

DHCF
Department of Health Care Finance

DC MEDICIAD PHARMACY & THERAPEUTICS (P & T) CORNER

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PHARMACY & THERAPEUTICS CORNER

Next P&T Meeting: 12/04/2025 @ 2pm

The last DC Medicaid Fee For Service (FFS) P & T Committee was held on Sept 4th, 2025. You may track updates of DC FFS Preferred Drug List (PDL) at District of Columbia Medicaid | Home. The public session of the quarterly P & T Committee is open to all. Visit the Prime Therapeutics DC FFS Provider Website to view all previous agendas, and meeting notices. The December meeting notice will contain registration instructions to attend the P&T public session as well as how to provide materials and/or make a presentation.

SICKLE CELL DISEASE (SCD)

SCD is a group of inherited blood disorders that create crescent or 'sickle' shaped red blood cells which are normally disc-shaped and flexible. Sickle shaped red blood cells cannot flow easily (firm and sticky) through the body's blood vessels and have a much shorter lifespan than disc-shaped red blood cells. Since sickled red blood cells do not flow easily and die faster than replaced, the amount of oxygen delivered throughout the body can be severely decreased. SCD is a lifelong illness. Symptoms of SCD are different for each person and can range in levels of severity. It can cause serious health complications such as frequent infections, painful tissue damage (vaso- occlusive event), stroke, acute chest syndrome, eye problems, kidney disease, etc.

In the early 1970s, the average lifespan of people with SCD was 14 years old. Today, people with SCD live to their fifties, and beyond due to significant advancement in management and therapy. These days, management of SCD involves comprehensive care, prevention, and treatment. Prevention strategies include a combination of lifestyle behaviors, medical screenings, vaccines, and blood transfusions.

Disease-modifying medications currently approved by the FDA to prevent or reduce pain crisis and other SCD complications are hydroxyurea, L-glutamine, and crizanlizumab. These prophylaxis medications can be taken to reduce the occurrence of complications. Interventions such as bone marrow transplants and gene therapies are treatment options for some patients.

Hydroxyurea is the first line medicine (standard for approximately 30 years) to prevent sickling and reduce complications of SCD. Hydroxyurea produces fetal hemoglobin (HbF) which does not sickle and has been shown to reduce the number of painful events by half. It has also been shown to reduce the need for blood transfusions and hospitalizations by improving anemia. Hydroxyurea may reduce stroke risk in children with SCD.

Some possible side effects of hydroxyurea include headache, nausea, darkening of nails, and may increase the risk of infection. Patients should avoid pregnancy since hydroxyurea may cause fetal harm. Baseline testing and continued monitoring of blood cell counts are required when taking hydroxyurea to determine dose adjustments. Hepatic and renal impairment dose modifications should be monitored and evaluated. To increase efficacy potential, it is important for an optimized dose to be taken around the same time each day. Hydroxyurea takes weeks to months for full effectiveness in preventing SCD complications. HbF levels should be monitored every three to four months for treatment efficacy.

L-glutamine (pharmaceutical grade) was approved in 2017 to reduce acute complications of SCD in patients 5+ years old. The mechanism of action (MOA) is not fully understood but believed to improve the NAD redox potential in sickle RBCs by increasing the availability of reduced glutathione. L-glutamine may regulate and prevent oxidative damage in RBCs. Compared to placebo, L-glutamine is associated with fewer acute pain events, hospitalizations/duration, and fewer patients with acute chest syndrome.

Common side effects are GI (constipation and nausea), headache, cough, and pain. There are many unregulated forms of L-glutamine available on the free market. Providers should ensure that SCD patients are administering pharmaceutical grade L-glutamine and dose accordingly based on body weight twice a day. Routine monitoring of renal and hepatic function is recommended in patients with impairment/ receiving IV parenteral nutrition since L-glutamine is metabolized to glutamate and ammonia.

Crizanlizumab is a monoclonal antibody IV infusion approved in 2019 for SCD patients 16 years and older to reduce the frequency of vaso-occlusive crisis. Crizanlizumab decreases blood cells from sticking together by attaching to the protein P-selectin. The European Medicines Agency (EMA) withdrew authorization in May 2023 based on the findings of no significant clinical effects from STAND phase III trial. However, it is still approved in the U.S. and the STAND trial is ongoing as of September 2025. As of today, the STAND study shows no significant difference in efficacy versus placebo while acknowledging debatable trial limitations but report a consistent safety and tolerability profile.

Some practitioners may still consider crizanlizumab in patients who have acute vaso-occlusive pain episodes unresponsive to hydroxyurea, L-glutamine, or both. SCD patients are monitored during and after infusion in a healthcare setting. Possible side effects are infusion-related reactions, nausea, stomach discomfort, joint pain, and back pain.

Cell-based gene therapy for the treatment of SCD was first approved by the FDA in 2023 with exagamglogene autotemcel (also known as exa-cel) and lovotibeglogene autotemcel (also known as lovo-cel) for patients 12+ years old with a history of vaso-occlusive events. Potential benefits of gene therapy for SCD include less pain fewer hospitalizations, and improved hemoglobin levels. Both gene therapies use the patient's own hematopoietic stem cells (autologous transplant). This method eliminates the need for immunosuppression and the risk of graft vs. host disease unlike an allogeneic blood and marrow transplant. SCD gene therapy is a six-month long commitment with several steps which are outlined for patients by the National Human Genome Research Institute. The conditioning and cell infusion step (~ 1 weeklong) includes chemotherapy which comes with its own risks and requires hospitalization. Even after the entire 6-month treatment, follow up for approximately 15 years is essential to identify and monitor any possible long-term effects.

Exa-cel's MOA with autologous hematopoietic stem cells is gene-edited therapy which ultimately increases HbF production. Lovo-cel's MOA with autologous hematopoietic stem cells is gene addition therapy which ultimately produces anti-sickling hemoglobin. Exa-cel nor lovo-cel were studied in renal or hepatic impairment. It is important for providers to assess renal and hepatic function to ensure autologous hematopoietic stem cell therapy transplantation is appropriate.

Exa-cel and lovo-cel have an extensive list of interactions, adverse effects, and warnings described in the FDA prescribing details. Notably, lovo-cel has a black box warning for hematologic malignancy.

PHARMACIST NUGGET (Bridging the Gap)

Frequent community pharmacy encounters with SCD patients are opportunities to counsel about current therapies along with latest gene therapy advancements. All pharmacists and providers should be aware that DC was approved to participate in The Cell and Gene Therapy Access Model (CGT) starting on January 1st, 2026. The CGT Access Model is a multi- year initiative led by the Centers for Medicare & Medicaid Services (CMS) to improve access to cell and gene therapies for Medicaid beneficiaries, particularly those with SCD. The following link provides more information about the program: CGT Access Model. Navigating general and especially the specialized healthcare system can be challenging. CMS provides a great roadmap example of CGT access. Community pharmacists should encourage SCD patients to explore with their hematology patient care team if CGT is suitable. Overall, treatment options will be based on factors such as age, type of SCD, response to other treatments, and health status. Criteria for exa-cel and lovo-cel are located on the DHCF Provider Home Page

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