Policy Update

Senate Finance Committee Eyes Kidney Care Components for New Bill

By Rachel Shaffer

Patients with kidney disease may see several positive changes to their ESRD care options in 2016. A bipartisan "Chronic Care Working Group" formed by the Senate Finance Committee recently released a white paper outlining policy changes they are interested in enacting this year—including several components related specifically to kidney care.

After soliciting input in June 2015 from ASN and other stakeholders in the medical community regarding opportunities to improve the care of people with chronic conditions and reduce related Medicare expenditures, the committee received more than 1000 suggestions. The white paper narrowed down the feedback to approximately 20 policy options, which are on the short list for inclusion in a piece of legislation to be introduced later this year. Among the suggestions are two provisions for which ASN advocated that are specific to patients with kidney disease and several that would have direct and positive benefits:

Expanding telehealth access for both home hemodialysis and home peritoneal dialysis

Permitting home dialysis patients to interact with their nephrologist for monthly visits via telehealth would create several benefits. Telemedicine may be valuable for ongoing care of patients residing in rural areas, who could avoid the need to travel in dangerous weather or for prohibitively long distances. Permitting patients and their physicians the option to participate in telehealth visits in some months—with in-person visits at least quarterly (every three calendar months)—may incentivize patients to adopt home dialysis as a treatment option.

In its comments to the committee,

BRIEF SUMMARY

AURYXIA™ (ferric citrate) tablets contain 210 mg of ferric iron equivalent to 1 g ferric citrate for oral use.

INDICATIONS AND USAGE
AURYXIA is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

CONTRAINDICATIONS
AURYXIA is contraindicated in patients with iron overload syndromes (eg, hemochromatosis).

WARNINGS AND PRECAUTIONS
Iron Overload: Iron absorption from AURYXIA may lead to excessive elevations in iron stores. Increases in serum ferritin and transferrin saturation (TSAT) levels were observed in clinical trials. In a 56-week safety and efficacy trial in which concomitant use of AURYXIA and IV iron was permitted, 55 (19%) patients treated with AURYXIA had a ferritin level >1500 ng/mL as compared with 13 (9%) patients treated with active control.
Assess iron parameters (eg, serum ferritin and TSAT) prior to initiating AURYXIA and monitor iron parameters while on therapy. Patients receiving IV iron may require a reduction in dose or discontinuation of IV iron therapy.
Accidental Overdose of Iron: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.
Patients with Gastrointestinal Bleeding or Inflammation: Patients with inflammatory bowel disease or active, symptomatic gastrointestinal bleeding were excluded from clinical trials. Safety has not been established in these populations.

ADVERSE REACTIONS
Adverse *reactions* to a drug are most readily ascertained by comparison with placebo, but there is little placebo-controlled experience with AURYXIA, so this section describes adverse *events* with AURYXIA, some of which may be disease-related, rather than treatment-related. A total of 289 patients were treated with AURYXIA and 149 patients were treated with active control (sevelamer carbonate and/or calcium acetate) during the 52-week, randomized, open-label, active control phase of a trial in patients on dialysis.
A total of 322 patients were treated with AURYXIA for up to 28 days in three short-term trials. Across these trials, 557 unique patients were treated with AURYXIA; dosage regimens in these trials ranged from 210 mg to 2,520 mg of ferric iron per day, equivalent to 1 to 12 tablets of AURYXIA. In these trials, adverse events reported for AURYXIA were similar to those reported for the active control group. Adverse events reported in more than 5% of patients treated with AURYXIA in these trials included diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%).
During the 52-week active control period, 60 patients (21%) on AURYXIA discontinued study drug because of an adverse event, as compared to 21 patients (14%) in the active control arm. Patients who were previously intolerant to any of the active control treatments (calcium acetate and sevelamer carbonate) were not eligible to enroll in the study. Gastrointestinal adverse events were the most common reason for discontinuing AURYXIA (14%).
AURYXIA is associated with discolored feces (dark stools) related to the iron content, but this staining is not clinically relevant and does not affect laboratory tests for occult bleeding, which detect heme rather than non-heme iron in the stool.

DRUG INTERACTIONS
Doxycycline is an oral drug that has to be taken at least 1 hour before AURYXIA. Ciprofloxacin should be taken at least 2 hours before or after AURYXIA. Oral drugs that can be administered concomitantly with AURYXIA are: amlodipine, aspirin, atorvastatin, calcitriol, clopidogrel, digoxin, doxercalciferol, enalapril, fluvastatin, levofloxacin, metoprolol, pravastatin, propranolol, sitagliptin, and warfarin. There are no empirical data on avoiding drug interactions between AURYXIA and most concomitant oral drugs. For oral medications where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, consider separation of the timing of the administration of the two drugs. The duration of separation depends upon the absorption characteristics of the medication concomitantly administered, such as the time to reach peak systemic levels and whether the drug is an immediate release or an extended release product. Consider monitoring clinical responses or blood levels of concomitant medications that have a narrow therapeutic range.

USE IN SPECIFIC POPULATIONS
Pregnancy: Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women. It is not known whether AURYXIA can cause fetal harm when administered to a pregnant woman. Animal reproduction studies have not been conducted.
The effect of AURYXIA on the absorption of vitamins and other nutrients has not been studied in pregnant women. Requirements for vitamins and other nutrients are increased in pregnancy. An overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes, and fetal malformation.
Labor and Delivery: The effects of AURYXIA on labor and delivery are unknown.
Nursing Mothers: Data from rat studies have shown the transfer of iron into milk by divalent metal transporter-1 (DMT-1) and ferroportin-1 (FPN-1). Hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.
Pediatric Use: The safety and efficacy of AURYXIA have not been established in pediatric patients.
Geriatric Use: Clinical studies of AURYXIA included 106 subjects aged 65 years and older (33 subjects aged 75 years and older). Overall, the clinical study experience has not identified any obvious differences in responses between the elderly and younger patients in the tolerability or efficacy of AURYXIA.

OVERDOSAGE
No data are available regarding overdose of AURYXIA in patients. In patients with chronic kidney disease on dialysis, the maximum dose studied was 2,520 mg ferric iron (12 tablets of AURYXIA) per day. Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used.
In clinical trials, one case of elevated iron in the liver as confirmed by biopsy was reported in a patient administered IV iron and AURYXIA.

PATIENT COUNSELING INFORMATION
Dosing Recommendations: Inform patients to take AURYXIA as directed with meals and adhere to their prescribed diets. Instruct patients on concomitant medications that should be dosed apart from AURYXIA.
Adverse Reactions: Advise patients that AURYXIA may cause discolored (dark) stools, but this staining of the stool is considered normal with oral medications containing iron.
AURYXIA may cause diarrhea, nausea, constipation, and vomiting. Advise patients to report severe or persistent gastrointestinal symptoms to their physician.

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ASN emphasized that patient safeguards are essential for a patient population that requires ongoing, intensive treatment. Both patients and physicians must retain the option to choose to conduct their monthly clinical assessment visit in-person if that more appropriately meets clinical needs in any given month. The committee's proposal is currently limited to permitting telehealth interactions that take place at dialysis facilities, but ASN continues to support allowing patients to interact with their nephrologist for some monthly visits from their own home.

Permitting patients with ESRD to enroll in Medicare Advantage plans

Under current law, people who develop kidney failure are not permitted to enroll in Medicare Advantage plans—ESRD is the only pre-existing condition that renders patients ineligible to participate in this program. ASN encouraged the committee to grant ESRD beneficiaries the same freedom of choice and access to improved care coordination services as other Medicare-enrolled individuals and will continue to support the committee's interest in including it in the final legislation.

Allowing patients with advanced kidney diseases to benefit from new and existing chronic care management (CCM) payment codes

The committee proposed developing a new code that would reimburse physicians who dedicate time to coordinating care for people with multiple high-severity chronic conditions. This concept builds upon a recently created code that reimburses for care of people with multiple chronic conditions (but which are not necessarily high-severity).

More than 50% of patients with chronic kidney disease have 5 or more co-morbid conditions, and CKD is included among 4 of the 5 most costly chronic condition combination triads in the Medicare program. CKD patients could benefit greatly from the proactive, comprehensive care coordination that the newly proposed high-severity codes would offer—providing them superior quality of life, fewer hospitalizations, and better long-term health.

Current CMS policy excludes patients with end-stage renal disease (ESRD) from eligibility for the existing CCM codes during the same 90-day period during which they receive standard—and lifesaving—dialysis care. This exclusion was not legislatively mandated, but rather, implemented during the CMS rulemaking process. ASN strongly believes that patients with kidney disease deserve equitable access to CCM services, and would be among the most likely to benefit from the new high-severity codes.

Among other beneficial policy recommendations the committee may include in its bill are quality measures for chronic conditions and commissioning of a study on medication synchronization. ASN will continue to interact with committee members and staff to build support for these and other policies as they move forward to drafting and introducing a bill. For more details concerning ASN's recommendations, please visit: http://www.asn-online.org/policy/webdocsAmericanSocietyofNephrologyASN.pdf.

President's 2017 Budget Shortchanges Kidney Research

By Grant Olan

On February 9, 2016, President Barack Obama released his budget proposal for 2017, the official start of the congressional budget process. Although the proposal includes increases for the National Institutes of Health (NIH) and other ASN priorities, it relies on budget gimmicks that some congressional appropriators are calling nonstarters.

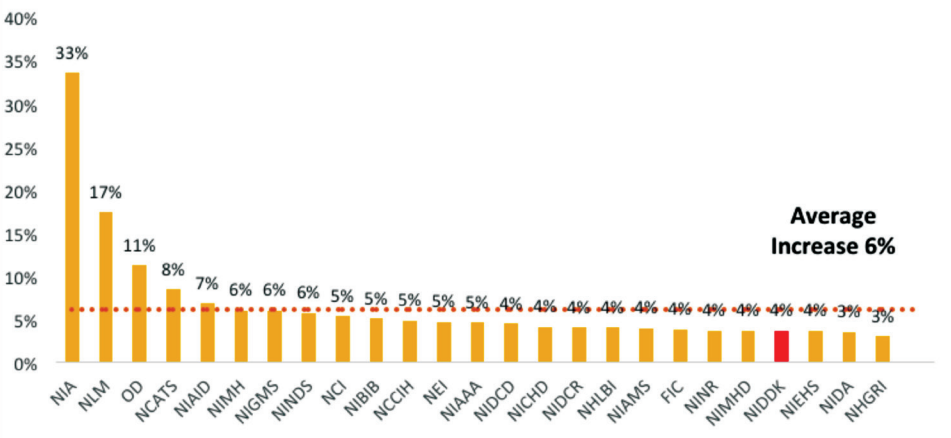
With those budget gimmicks, the President's proposal would increase NIH funding overall by $825 million for a total of $33 billion. However, the entire increase would go to a handful of administration priorities that include the Cancer Moonshot, Precision Medicine Initiative, and BRAIN (Brain Research through Advancing Innovative Neurotechnologies) Initiative. None of the additional funds would go to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and most of the other 26 institutes and centers are similarly shortchanged. Instead, NIDDK's budget for 2017 would remain flat at $1.966 million.

"ASN commended President Obama in 2016 for his bold leadership in securing a budget increase for NIH and NIDDK," ASN President Raymond C. Harris, MD, FASN, recalled. "Regrettably, his 2017 budget proposal would shortchange NIDDK and kidney research. Change is on the way because of advances made through NIDDK-funded kidney research. Additional funding is needed to accelerate these and other novel therapies that could improve the care of patients with kidney disease and result in significant savings to Medicare," Harris said.

ASN, in partnership with more than 200 patient and voluntary health groups, medical and scientific societies, and academic and research organizations, is advocating for a 2017 request for NIH of $34.5 billion, about a 7% increase over 2016. As a leader in Friends of NIDDK, a coalition that advocates collaboratively for increased NIDDK funding, ASN is spearheading the kidney community's efforts to advocate for a 2017 budget request for NIDDK of $2.165 billion, about a 10% increase over 2017. NIDDK ranked near the bottom of the list of NIH 2016 funding increases by institute and center (Figure 1).

"The story of cancer, heart disease, and HIV/AIDs is clear. Researchers go where the dollars are and funding increases drive innovation," ASN Research Advocacy Committee Chair Frank "Chip" Brosius, MD, commented. "HIV/AIDs went from a death sentence in the 1980s to essentially a chronic disease today. That kind of progress is possible with kidney disease if we are visionary enough to provide NIDDK sustainable funding increases for kidney research."

Figure 1. NIH funding increase by institute and center



Statement on President Obama's 2017 Budget Proposal

By ASN President Raymond C. Harris, MD, FASN

Looking back to this time last year, ASN was commending President Obama for his bold leadership in securing a budget increase for NIH and NIDDK in 2016. Regrettably, his 2017 budget proposal would shortchange NIDDK and kidney research. Kidney disease affects more than 20 million Americans and costs Medicare $80 billion. The Medicare End-Stage Renal Disease Program alone costs $35 billion, more than NIH's entire budget. Yet federal investments in kidney research are less than 1% of total kidney care costs.

There have been several major breakthroughs in the past several years thanks to NIDDK-funded research. For example, geneticists focused on the kidney have shaped our understanding of the pathogenesis of nephrotic syndrome and chronic kidney disease. Just last year, scientists announced a method for growing new kidneys in a laboratory as well as a rapid method for screening new prescription medications using kidney cells that would spare the expense and time of conducting human clinical trials.

Change is on the way because of advances made through NIDDK-funded kidney research. Additional, sustained funding is needed to accelerate these and other novel therapies that could improve the care of patients with kidney disease and result in significant savings to Medicare. A failure to maintain and strengthen NIDDK's ability to support the groundbreaking work of researchers across the country carries a palpable human toll, denying hope to the millions of patients awaiting the possibility of a healthier tomorrow.