
Renal anemia and hyperphosphatemia, or elevated serum phosphorous, are two primary complications of chronic kidney disease (CKD) that are treated with erythropoiesis-stimulating agents (ESAs) and phosphate binders, respectively. The market for renal anemia drugs is poised to expand owing to the growing size of the CKD non-dialysis (CKD-ND) and dialysis patient populations, as well as the expected launches of novel therapies such as oral hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitors to treat renal anemia (roxadustat, AKB-6548, GSK-1278863A, and molidustat). This report examines the dynamics that will limit or promote market access for emerging oral HIF-PH inhibitors in the pipeline as new drug launches are expected as early as 2018. We analyze physician prescribing of ESAs, future prescribing practices, the impact and uptake of oral HIF-PH inhibitors on current therapy use, and formulary decision making for current and emerging agents, among other topics.

Questions Answered in This Report:

- Understand nephrologists’ perceptions and attitudes toward currently marketed and emerging renal anemia therapies, and uncover prescribing trends. Among the CKD-ND patient population, more than 80% of surveyed nephrologists prescribe ESAs such as darbepoetin alfa (Amgen’s Aranesp) or epoetin alfa (Janssen’s Procrit); dialysis patients are predominantly treated with epoetin alfa (Amgen’s Epogen). How do clinicians view current ESAs? How will medical practice for the treatment of renal anemia change in light of new therapies such as oral HIF-PH inhibitors and biosimilars poised to enter the U.S. market? What factors, including market access decisions by managed care organizations (MCOs), most strongly influence and constrain physician prescribing of new agents over currently available treatments? Do nephrologists expect to prescribe emerging oral HIF-PH inhibitors before or after ESA treatment? How has the dialysis bundle impacted the use of ESAs in the dialysis setting? What do nephrologists believe are the advantages and concerns associated with oral HIF-PH inhibitors? What factors will drive any changes in prescribing? How will iron-based binders such as Keryx Biopharmaceutical’s ferric citrate impact renal anemia treatment?

- Learn how prescribers plan to integrate emerging therapies and the HIF-PH inhibitor drug class
into their treatment plans. Physicians anticipate more prescriptions for HIF-PH inhibitors if these emerging therapies are placed on a preferred rather than a nonpreferred tier in both CKD-ND and dialysis patients. How will the new drugs’ safety, efficacy, and tolerability profiles set them apart from one another and from members of existing drug classes? Which drug and patient characteristics will most influence prescribing decisions by clinicians and formulary positioning by payers? What are U.S. clinicians’ and payers’ perceptions of the safety and side-effect profiles of the new renal anemia drugs? Will the HIF-PH inhibitors’ oral formulation—their only form of delivery—be a significant barrier to prescribing this novel drug class?

- Gain insight on the changing dynamics of the U.S. managed care reimbursement environment as they pertain to pharmacotherapy for renal anemia. Emerging therapies will need to convincingly demonstrate cost-effectiveness relative to existing agents to secure optimum reimbursement status given that MCOs appear fairly receptive to reimbursing oral HIF-PH inhibitors in their commercial plans if they are priced similar to or lower than ESAs. What are payers’ and prescribers’ expectations for the safety and efficacy of novel renal anemia drugs? What kind of reimbursement restrictions will be applied to the novel HIF-PH inhibitors? How do commercial and Medicare prescription drug plans assign tier positioning for new renal anemia market entrants? How will the price of novel agents influence formulary placement?

Scope:
- Primary research: This report is based on a survey of 101 nephrologists and 31 pharmacy/medical directors (PDs/MDs) at MCOs and examines the dynamics that will limit or promote market access for emerging CKD-ND and dialysis renal anemia therapies in the pipeline.
- Screening criteria: Nephrologists were required to be in practice for 2-30 years and have a minimum of 50 dialysis and 100 CKD-ND (stages 3 and 4) patients under their management. MCO PDs/MDs had to offer a Medicare Advantage plan and cover 100,000 lives or greater.
- Field dates: The physician surveys were conducted between August 20 and August 29, 2014; surveys of MCO PDs/MDs were conducted between August 20 and August 25, 2014. Surveys were completed over the internet.
- Report: PowerPoint format with 146 pages of content.

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