POINT OF VIEW:

Trump's proposed International Pricing Index (IPI) payment model for Medicare Part B drugs is another disruptive proposal that would hit hard at some of the biopharma industry's best selling products

This latest proposal–coined the IPI model–is part of several recent and forthcoming programs designed to follow through on the Trump administration's promise to lower prescription drug prices.

Pillars of the IPI model

Under the new proposal (being rolled out by the US Department of Health and Human Services [HHS] through the Centers for Medicare & Medicaid Services [CMS]), the prices reimbursed by Medicare for select physician-administered drugs will be aligned more closely with the average price paid by a basket of other countries. This is a form of what the global industry refers to as "international reference pricing (IRP)" and has been a part of drug reimbursement controls in Europe and other markets for decades. Prices of US Medicare Part B therapies are considerably higher than Europe and the rest of world. An HHS analysis estimates the US price is 1.8 times that of a selection of Medicare Part B drugs in 16 developed countries.

This new model aims to replace a key provision of Medicare Part B drug reimbursement, which today involves paying healthcare providers (eg, doctors, hospitals, and infusion clinics) the drug's average selling price (ASP) plus a 4.3% to 6.0% add-on payment. Policymakers aligned with Trump's blueprint have targeted the current model as an incentive for physicians to prescribe the most expensive drugs, raising overall healthcare costs. Under the new IPI model, physicians will no longer take on the financial risk associated with buying and billing drugs. Instead, providers will be paid a flat drug administration fee plus an add-on amount to ensure they do not lose

revenue relative to the prior buy and bill model. New private sector entities–referred to as vendors–will take on the financial risk of buying, supplying, and billing the government for Part B drugs. To avoid the low enrollment and eventual discontinuation that doomed the similar, voluntary Competitive Acquisition Program (CAP) that ran from 2006 to 2008, the new IPI model will be mandatory in regions where it will be tested.

Under the IPI, if a drug's ASP is higher than the international average price, Medicare will reimburse vendors at a target price derived from an international index and phased in over 5 years. It is hoped that vendors will compete for provider business on service and innovative inventory management offerings. Vendors will not be allowed to use drug formularies that prefer some drugs to others.

The IPI model will be open for public comment; CMS hopes to issue a formal rule in the spring of 2019, and begin pilots in select geographies in the spring of 2020.

Impact

Many stakeholders responded with strong opposition to the IPI model announcement last week.

For US oncologists, many of whom are still are actively invested in the full spectrum of drug infusion care for patients with cancer, this policy could have major implications to how they practice medicine. The Community Oncology Alliance (COA), an advocacy group for community oncologists, immediately issued a statement last week noting their concerns, including lack of practical implementation details, risks of resurrecting the failed CAP program, and general concern that such a disruptive approach would limit timely and unrestricted access to life-saving cancer treatments.

The biopharma industry was also quick to point out major flaws in what appears to be a disguise for direct government price control. The Biotechnology Innovation Organization (BIO) issued a statement saying that instead of ending "foreign free-loading," as Trump promises, the IPI model "embraces it and exacerbates its harmful effects."

Even some prominent health economists who favor US drug pricing and reimbursement reform point out the irony of politicians who stand firmly against socialized medicine putting forth a policy that effectively imports it.

Some of the industry's biggest manufacturers of oncology, immunology, and eye care products stand to lose significant revenue if such a policy were to be widely implemented.

Entrée Health's point of view

It is tempting to look at this proposal as another highly political volley from the Trump administration trying to back its promise to middle America leading up to the midterm elections. To some, it may make sense to sit back and let the dust settle, as it seems almost too distracting for pharma to address all at once.

However, careful consideration of policies put forth by the administration over the past year suggest biopharma must not only enhance its lobbying positions, but begin to make serious plans as alternative payment models become mainstream and reimbursement and pricing are more constrained than ever before. With the emergence of gene therapies and novel antibody-drug conjugates, physician-administered Medicare Part B products will continue to be an important part of biopharma's innovation mix. Here it seems the scales are tipping in the Medicare Part B space (where biopharma has enjoyed minimal price and access restriction) toward reforms that could drastically alter the playing field and create a new mix of organized providers and suppliers.

In addition to the IPI model proposal, this week the administration posted another proposal to the OMB website on pricing and patient cost sharing in Medicare Part D. This is further evidence that this administration is serious about finding solutions to control drug costs, and potentially has much greater impact on pharma given that Part D medication spend is 5 times that of Part B. Experts believe this new proposal will still avert government negotiation powers for Part D, but it is likely to include elements signaled in the President's Blueprint such as empowering Medicare D formularies to

carry only one drug instead of two, limiting OOP costs to seniors once they pass the $5,000 annual cost threshold, and requiring Part D plans to pass along a percentage of of rebates to patients.

Considerations for biopharma manufacturers

In the wake of this latest policy announcement, US market access managers should consider the following in the coming months:

- Engage global access colleagues and assess the international price exposure of their Medicare Part B portfolio. Misuse of IRP policies has been fought off in Europe in the past; a review of EFPIA (European Federation of Pharmaceutical Industries and Associations) positions on IRP in Europe is a worthwhile exercise for government and corporate planning executives
- Scenario plan for an evolving mix of US organized customers and reimbursement dynamics. Not only should the new IPI vendors and channel players be in the mix; it's time for a full evaluation of the many dynamics occurring in the space (eg, 340B centers facing lower reimbursement, providers moving out of IDNs back to community, providers abandoning B&B and focusing on patient care, growing exposure to clinical pathways and step therapy, etc)
- Educate and activate government affairs teams to help craft a prioritized plan of policy defense. Develop plans to integrate US and ex-US government affairs and advocacy planning and identify areas of common agenda for aligned global strategy as access policies continue to converge

For more information on how Entrée Health can help your organization navigate market access and communicate value to payers, contact Andrew Gottfried at agottfried@entreehealth.com ***or 212-896-8026.***