



PIRC Meeting

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PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Purpose

- Speak loudly with one voice
- Provide **a rare cancer perspective**
 - *Educate ourselves (& our communities)*
 - **Applaud** what we can
 - **Prepare** for what is coming
 - **Fight** against what must change
 - NOW AND NEXT YEAR
 - PREPARATION



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Agenda

- Recap – PIRC Submission in Follow-up to Round Tables and Town Hall
- Draft Guidance for IPAY 2028
- Discussion:
 - Feedback – “smoothing”
 - Feedback – impact of Part D redesign on formularies, utilization management
 - Cumulative impacts on innovation in rare cancers
- Follow Ups/Next Steps

PIRC Post-Stakeholder Engagement Submission to CMS



Outlined the challenges in developing rare cancer treatments, importance of post-market studies, and barriers to generic market entry in oncology treatments



Urged CMS to further refine its stakeholder engagement initiatives

Enable dynamic dialogue with CMS

Tailor questions to condition and treatment

Improve applicability of submission portal to patient advocacy organizations



CMS should use the discretionary authority granted for selecting drugs to delay selection of:

Small molecules that would be ineligible under the timeline for biologics (pill penalty)

Drugs with any NDA/BLA not meeting timeline for negotiation eligibility (QSSD)

IPAY 2028 Draft Guidance – Eligibility for Selection

No change to orphan drug (orphan exemption) or low spend Medicare drug exclusions (\$200M or less in Medicare spending)

Biosimilar delay - New policies proposed for submitting “Additional Delay Requests” and for “penalizing” manufacturers for failure of a biosimilar market entry.

- Selected in next cycle
- Rebate owed for years that an MFP would have applied if not for delay

CMS proposes to identify drugs eligible for small biotech exclusion on two separate tracks, one for Part B and one for Part D expenditures. *A drug will be excluded if it qualifies under either track. **CLL Society successfully advocated for this interpretation of the statute.***

Draft Guidance for IPAY 2028 – Changes to Policy on Fixed Combination Products

For first 2 cycles, CMS considered a fixed combination drug containing two or more active moieties or active ingredients as distinct from a product containing only one of those active moieties or ingredients.

For IPAY 2028, CMS adds a caveat that “there may exist fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference.”

- How will CMS determine whether ingredient/moiety is biologically active?
- Example not meeting criteria was ingredients impacting bioavailability but not making a distinct and clinically meaningful difference
- This would conflict with Medicaid rebate provisions
- Impact in rare cancer?

IPAY 2028 Draft Guidance – Drug Selection Process

CMS will identify the 50 highest spend drugs under Part B and the 50 highest spend drugs under Part D.

- For Part B drugs, CMS will use Part B claims from 11/24 through 10/25 and calculate total amount, including beneficiary coinsurance

CMS will then combine total expenditures under Part B and Part D for the 100 drugs, rank them, from highest to lowest.

- CMS will select the 15 highest ranked drugs based on their combined Part B and Part D expenditures
- Biologics eligible for delay will be removed from the list
- When biologics are removed from the set of selected drugs, CMS could either move to the next drug/biologic or negotiated the remaining products included in the set of 15 highest cost drugs. It is not clear what the Agency will do.

IPAY 2028 Draft Guidance – Setting the “Maximum Fair Price”

The statute and draft guidance calculate a single MFP across all dosage forms and strengths, CMS has been using 30-day supply and seeks comment on ‘per-unit’ basis instead.

- Moving to per-unit pricing would reduce the potential that individuals receiving lower doses would experience a price increase.
- It would account for differences in 30-day supply when weight-based dosing is required or when doses are dependent on indication, age, or patient-specific factors.
- Should a single MFP be set on a per-unit basis as opposed to the 30-day equivalent supply basis?

CMS proposed additional considerations for MFP ceiling calculations

- For a selected drug covered under Part D but not under Part B, the sum of the plan-specific enrollment weighted amounts for a 30-day supply
- For a selected drug payable under Part B and not covered under Part D, a weighted average for a 30-day supply using the lesser of WAC or ASP, not adjusted for sequestration.
- For Part B drugs also covered under Part D, an amount equal to the weighted average, per 30-day equivalent supply of each NDC-9, using the amounts calculated above for Part B and Part D drugs. CMS refers to this as the “combined Part B and Part D amount”).

IPAY 2028 Draft Guidance – Information on Selected Drug and Therapeutic Alternatives

CMS requests feedback on whether to collect additional forward-looking “market data” (forecasted net revenue and volume) for the negotiation period and/or price applicability period (i.e., “current” year and subsequent 2 years), such as forecasted net revenue and volume.

Alternative Part D therapies would be priced at the lower of either: the Net Part D Plan Payment and Beneficiary Liability, net of discounts, or the MFP negotiated for a prior year.

When CMS looks to Part B alternative therapies for pricing, it will use lesser of ASP or WAC.

For drugs with multiple therapeutic alternatives, CMS will consider therapeutic alternatives within each indication and weight prices by utilization or other patterns of use. ***This reduces impact of rare cancer uses in calculating price. CMS seeks comments on alternative methodologies.***

CMS also seeks comment on the “possibility and feasibility” of considering Part A or Part B services as potential therapeutic alternatives – this issue will be explored in the rulemaking required for cycles beginning with IPAY 2029.

CMS Seeks Comments on Ways to “Effectuate” the Negotiated Price for Part B Drugs

CMS is soliciting comments on how MFP actually gets to physician offices/outpatient centers compared to how it gets to the Part D plan/pharmacy.

- How much extra burden will providers face in administering Part B drugs with an MFP?
- What impact will an MFP have on clinician reimbursement and willingness to administer drugs in the clinician office or hospital outpatient setting?
- This is about “+6” as well as burden on offices to track if they get MFP when they buy the drug (b/c they’re storing it a while and won’t know until later if its administered to Medicare or commercial patient)



IPAY 2028 Draft Guidance - Renegotiation

- CMS **must select** previously-negotiated drugs with a change in monopoly status for re-negotiation (...longer monopoly)
- Other re-negotiation eligibility triggers are:
 - Newly added indications – CMS may include off-label uses identified in evidence-based clinical practice guidelines or NCCN compendia as a trigger for renegotiation.
 - THIS REPRESENTS A SIGNIFICANT DETERENT TO INDUSTRY-SPONSORED POST-APPROVAL STUDIES
 - Material change in any factor in section 1194(e) of the Act (e.g., change in alternative therapies).
- **CMS also must select** drugs for which renegotiation would “result in a significant change”
 - CMS propose significant change as over 15% or more
 - CMS expects to get its renegotiation eligibility information through voluntary manufacturer submissions and publicly available information.
- Statute requires renegotiation begin 2028, when some already selected drugs may already have been a longer monopoly. CMS proposed reaching back to November 2025.
- Part D drugs with Part B expenditures are likely to be selected for re-negotiation.

IPAY 2028 Draft Guidance – Renegotiation Process and Renegotiated MFP Availability

CMS proposes to collect new data for all drugs selected for renegotiation from manufacturers and interested parties and does not propose changes to data elements used in original negotiation.

CMS will not offer or agree to a counteroffer of an MFP greater than the ceiling price in the previous negotiation.

- Adjustments would be made to account for part B data, inflationary adjustments, and similar factors
- AGAIN, the potential for re-selection triggering a new, lower MFP for drugs with follow-on indications (or off-label uses within accepted guidelines (NCCN)) is very likely to chill research in indications w/o sufficient volume to counter pricing decreases.

Primary Manufacturers must make the initial MFP available for all dispenses to MFP-eligible individuals on or before December 31, 2027, and the renegotiated MFP available, if applicable, for dispenses on or after January 1, 2028.

DISCUSSION

Patient feedback on signing up for and using the “smoothing” mechanism

Any reported changes in Part D impacting patient access or finances?

- Premium increase/decrease?
- Formulary changes?
- New or “enhanced” utilization management barriers?



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Next Steps

Review, sign on to PIRC submission

Comments to IPAY2028 Due June 26

- QSSD
- Pill Penalty
- Feedback from PIRC members

NEXT PIRC CALL: July 14