CARA THERAPEUTICS

Protect Access to Breakthrough Therapy:

KORSUVA®(difelikefalin) Injection for CKD-aP in Hemodialysis Patients

May 15, 2023

Goals for Discussion

- Provide update on status of patient access to KORSUVA and challenges encountered during launch
- Discuss post-TDAPA RFI policy recommendations and implementation issues
- Address questions from OMB
- Next Steps

CARA

KORSUVA Launch Update

- KORSUVA delivering on promise seen during clinical program
  - Break-through effectiveness and safety profile proven in clinical program is translating to post-approval commercial setting
  - Patients and clinicians reporting good results
  - Early proxies of effectiveness positive (e.g., clinic reorder rates)
- Early Launch Focus
  - Establish contracts with key providers
  - Educate prescribers, clinic staff, and patients on the condition
  - Identify appropriate patients for treatment
  - Support community in implementation of protocols and systems for administration and billing of KORSUVA

CARA

KORSUVA Launch Update – Challenges to Access

- Uncertainty around post-TDAPA reimbursement status is a key reason for slower-than-expected uptake and limiting patient access
  - Common concern that patients will have to come off drug for lack of reimbursement post-TDAPA causing many to take "wait and see" approach before initiating therapy even during TDAPA period
- Non-reimbursement related factors seen with any breakthrough drug launch
  - Clinician and patient awareness about potential solution for a previously largely untreatable condition
  - Logistical and implementation issues typical of a new drug adoption at dialysis clinics
- Labor and staffing challenges and shortages
- Medicare Advantage contracting challenges

Adoption of post-TDAPA adjustment payment in CY 2024 ESRD Rule essential to appropriate patient access to KORSUVA

CARA

CMS Post-TDAPA RFI - Policy

- We support the non-budget neutral add-on adjustment in RFI
  - Creates a targeted policy
  - Assures that decision to use KORSUVA is made by providers and patients and not unduly influenced by economic considerations
  - Especially important with innovative new therapies like KORSUVA where 1) the product will be used in a fraction of the overall ESRD population and 2) no money currently exists in the payment system to treat this serious condition

- All drugs receiving TDAPA should be eligible for add-on adjustment
  - Current TDAPA new drug standard objective, predictable and easy to implement
  - Add-on adjustment methodology avoids incentives to artificially inflate utilization that is then diverted away from patients in need of the therapy – clinical necessity can carry the day

- Any offset should correspond to reductions in expenditures for formerly separately reimbursed drugs *that were caused by the inclusion of the new drug*

CARA

CMS Post-TDAPA - Implementation

- Add-on adjustment should be set at the per treatment cost for the "average" patient using the product, using utilization and cost information from last quarter of TDAPA period
  - In Korsuva's case:
    - Korsuva supplied on a single-dose vial basis*
    - One vial required for vast majority of patients, only a very small percentage require two vials (approx. 2-4 %)
    - For example, if the average number of vials used averages out to 1.05 vials/treatment, add-on adjustment equals ASP/vial x 1.05

- Critical that add-on adjustment is available seamlessly after TDAPA period ends to avoid disruption to patient access and clinical care plan

- Update cost parameter annually using a relevant index to capture inflationary pressures
  - PPI Commodity for Pharmaceuticals for human use

- Given negative impact of post-TDAPA uncertainty, it is critically important to recognize utilization likely to increase if a post-TDAPA policy is finalized
  - Essential to make sure that patients who medically require Korsuva can access it

**FDA prescribing information provides that "KORSUVA injection is supplied in a single-dose vial. Any unused drug remaining after injection must be discarded."*

CARA

Next Steps

- We believe adoption of a predictable, new money post-TDAPA add-on adjustment for products like KORSUVA in the next rulemaking cycle is essential to ensure patient access and allow for future new innovation
- What information or support does the Administration need to support its ongoing deliberations?

CARA