Provision of IV selenium in PN: Price, not shortage is now the challenge

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Background

Drug shortages have plagued the PN industry for over a decade with every single component of PN affected since 2010. It is estimated that generic injectables (many used in PN compounding) made up for 55% of shortages in 2018. Reports of patient morbidity and mortality have been worst case result, but considerable ongoing increases in pricing of ingredients has also presented a challenge, particularly for home PN providers.

Previous IV selenium AWP was $0.05 per mcg, with the new selenious acid at $0.69 — a 12.5 fold increase. For a typical adult dose of 60mcg, this went from $3 per dose to $41.40. Purchasing groups negotiated some discounts, but pricing remains high creating concerns for patient safety if doses are reduced, eliminated, or organizations attempt production of a selenium product.

Recommended adult dose of IV selenium is 60-100 mcg/day and 1-3 mcg/kg/day for neonatal /pediatric patients. Unlike adult IV trace element (TE) combination products, neonatal and pediatric combinations do not provide selenium; it must be added separately. Some long term adult PN patients require individualized TEs due to higher levels of some TE's in the combination.

IV TEs have never gone through FDA review and approval process. In July 2019, selenium was the first TE reformulated and FDA approved. Upon release, pricing increased anywhere from 12-20 fold, causing some providers to treat the provision of IV selenium as a shortage situation.

Methods

This home infusion provider re-assessed every patient in a 45+ pharmacy network regarding the need for IV selenium. Cost per 60 mcg dose was $20-- IF none of the vial is wasted, since the 10 ml vial cost is approximately $200. Average home infusion reimbursement for PN per day ranges between $120-130 total for adults, not including nursing.

Actions taken by this provider included:

- Pediatric/neonatal selenium dosing was reassessed for NPO patients.
- TE blood levels were ordered for adults who received individualized TE for more than 3 months to evaluate if MTE could be reinstated.
- Adult patients receiving selenium in addition to a multi-trace combination were reassessed for needs >60 mcg/day; if possible doses were reduced.
- Adult patients with absorptive capacity/a duodenum who could not use a multi-trace combination product were provided with oral selenium supplements (200 mcg) with a plan to check trace element levels in 3 months.
- Each patient's insurance was checked for the possibility of billing for additional additives/ drugs as per the NHIA's recommendation. MTE and individual TEs are usually included in the per diem rate.
- Clinicians in the organization are encouraged to be involved in industry/consumer efforts to lobby for patient safety and reasonable drug pricing.

Discussion

Patients who need PN should have access to safe and appropriate PN therapy that provides required nutrients in the doses needed. If the cost of the PN formula becomes greater than hospital or homecare reimbursement rates, access to home PN and patient safety will be at risk.

Conclusions

Nutrition support clinicians should remain apprised of pricing and shortage challenges and monitor for unsafe practices within their organizations.