

New Specialty Medication Onboarding Checklist

Step 1: Medication Identification & Access

- ☐ Confirm specialty pharmacy has access
 - ☐ Check to see if medication is available from wholesaler. If it is not, ask wholesaler if the medication can be loaded. If it cannot be loaded, reach out to the manufacturer directly.
 - ☐ Review limited distribution requirements, [REMS requirements](#), contracting requirements and document enrollment (if applicable)
 - ☐ Confirm ordering pathway and vendor setup
 - ☐ Assess ordering across accounts (340B, wholesale acquisition cost [WAC] access, and/or group purchasing organization [GPO])
 - ☐ Identify any special ordering processes (wholesalers vs manufacturer)

Step 2: System Build & Billing Validation

- ☐ Build medication in electronic health record (EHR) and dispensing software
- ☐ Confirm packaging sizes and unit conversions (esp. for biosimilars)
 - ☐ Evaluate billing units and mitigate risk
 - ☐ Add product notes or alerts for special billing or dosing considerations
 - ☐ Block incorrect or mismatched NDCs (biosimilars, pack sizes)
- ☐ Complete clinical builds in patient management program software if applicable
 - ☐ Identify any specific documentation or clinical management needs, including: tailored monitoring, collaborative practice agreements or ability for therapeutic interchanges, REMS compliance tracking, rare disease requirements
- ☐ Write [proactive risk assessment](#)
 - ☐ Evaluate for ancillary supplies (sharps containers, etc.)
- ☐ Add medication to appropriate lists in all applicable systems (hazardous, formulary, internal, marketing, EHR medication lists, REMS)

Step 3: Inventory Preparation

- ☐ Consider potential volume and inventory level
- ☐ Confirm supply chain requirements (storage, shipping, hazardous classification, DSCSA considerations)
- ☐ Ensure storage space is ready (refrigerated, hazardous, etc.)
- ☐ Validate first-order quantity based on use case and pack size

Step 4: Team Training & Communication

- ☐ Train pharmacy staff (dispensing, clinical, operational)
- ☐ Create or update patient education materials
- ☐ Send interdisciplinary communication (administration information, clinical, inventory, billing)
- ☐ Communicate with ordering providers regarding product availability for dispensing

Step 5: Evaluation of Other Considerations

- ☐ Evaluate REMS, manufacturer requirements
 - ☐ Audits
 - ☐ Workflow modifications
- ☐ Set up reporting requirements (data feeds, inventory report, REMS etc.)

Step 6: Post-Launch Follow-Up

- ☐ Review first dispense outcome
- ☐ Review packaging or quantity issues
- ☐ Update standard operating procedures (SOPs) as needed
- ☐ Evaluate onboarding steps for refinement