Specialty Drug Proactive Risk Assessment

Drug Name: Alunbrig (brigatinib)
Date Risk Assessment Prepared: 8/15/2024

Consideration	Risk Assessment	Notes	Organization Assessment	Action Required/Assignment	Date Completed
General					
Is it a look-alike or sound-alike (LASA) name with another medication?	Yes Brigatinib may be confused with abrocitinib, baricitinib, crizotinib, neratinib, trametinib, or vigabatrin.[3,7-9]				
Are there other drug names that begin with the same first three letters? • If yes, do the products have other overlapping/similar characteristics (e.g., dosage strength, dosage form, indication/purpose)?	Yes Multiple aluminum containing drugs may start with "ALU" and are available as oral formulations; however, they are unlikely to have overlapping strengths or indications. Multiple other drugs start with "BRI." Briellyn, Brilinta, and brivaracetam (Briviact) are available as oral formulations, with Brilinta supplied as a 60 mg and 90 mg tablet. However, none of these medications are likely to share an overlapping indication with brigatinib.[2,3,8]				
How is this medication displayed in a drop-down menu and other drug name fields? (Consider how the display of the medication name may contribute to confusion or a selection error) • Are there character limit considerations (e.g., what will display in the drug name field)? • Will the medication name need to be truncated or abbreviated? • If there are multiple strengths/concentrations, do they differ by factors of 10 or 100? How are these strengths ordered in a drop-down menu? • If a combination product, in what order are the ingredients displayed? Do they match the container label? Can you see all the ingredients? Do they appear near other combination or single ingredient products with the same ingredients?	**Pharmacy to review their software.** No – Strengths/concentrations do not differ by a multiple of 10 or 100. No – This medication is not a combination product.[1]				
Is this medication a controlled substance, high-alert medication, and/or hazardous drug? • If yes, are there handling processes in place? How often are staff trained and reassessed on handling precautions? Who will be conducting/leading the training?	No – Not a controlled substance. Yes – Brigatinib is a high-alert medication. Potentially hazardous – Brigatinib is not included as a proposed addition to the NIOSH 2020 Draft list; however, it may cause fetal harm. Evaluate pregnancy status prior to therapy initiation. Advise females of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose. Male patients with partners who could become pregnant should use effective contraception during therapy and for at least 3 months after the last dose. Breastfeeding is not recommended during treatment and for 1 week after the last dose. Brigatinib may cause reduced fertility in males. Brigatinib may also cause other organ toxicities.[1-3,5,6,10,11] **Pharmacy to establish and define additional handling processes and training procedures if needed.**				
Does the product have an approved Risk Evaluation and Mitigation Strategies (REMS) with action required prior to purchasing and dispensing?	No[1,4]				
Does the product contain latex?	No[1]				
Has ISMP written about errors with this medication?	No				
Selection, Ordering, and Procurement					
Is this a Limited Distribution Drug (LDD)? • If yes, does the pharmacy have access to it?	Yes – Alunbrig is a limited distribution drug available through Biologics and Onco360 specialty pharmacies. Additional access guidance can be found by visiting: https://www.alunbrig.com/hcp/sites/default/files/resources/alunbrig-access-guide.pdf.				
From where is this medication obtained (e.g., wholesaler, manufacturer)? • How long does it take for this product to arrive? • Are there unique ordering requirements (e.g., direct from the manufacturer)?	Alunbrig is distributed through specialty distributors, including ASD Healthcare, Cardinal Health, McKesson Plasma and Biologics, and Oncology Supply. Additional distribution guidance can be found by visiting: https://www.alunbrig.com/hcp/sites/default/files/resources/alunbrig-access-guide.pdf.				
What are the available dosage forms for this medication (e.g., tablet, capsule, pen, syringe, vial)?	Tablet, oral[1-3]				
What are the available strengths/concentrations/vial sizes?	Tablet, oral: • 30 mg • 90 mg • 180 mg[1-3]	**Notes:** • 30 mg tablets are supplied in a 30-count bottle. • 90 mg tablets are supplied in 7-count and 30-count bottles. • 180 mg tablets are supplied in 7-count and 30-count bottles. • A combination single-carton, one-month initiation pack is also available. It contains one bottle of 90 mg tablets (7 count) and one bottle of 180 mg tablets (23 count).[1]			
Storage and Handling					
How will this product be stored? Specific storage requirements to consider: • Refrigerator • Freezer • Room Temperature • Protect from light • Process for hazardous medication storage	Room Temperature: Store at 20°C to 25°C (68°F to 77°F).[1-3] Per an email exchange with a representative from Takeda Oncology (Aug 2024), Alunbrig should be stored in the original container to protect from light. **Pharmacy to consider and define additional storage processes and training procedures if needed.**				

Where will this product be stored to avoid product mix-ups with other products (e.g., look-alike names, look-alike packaging)?	**Pharmacy to review specific storage options.**	Consider storing away from other LASA medications. For all storage locations, ensure there is adequate space to accommodate this new product (e.g., separate shelves/dividers).			
Is it required to remain in the original manufacturer package?	Yes – Per an email exchange with a representative from Takeda Oncology (Aug 2024), Alunbrig should be stored in the original container to protect from light.				
Is it appropriate to store in automated dispensing systems (e.g., robotics)?	Given the potentially hazardous classification and to reduce the risk of potential cross contamination, do not store loose tablets in an automated dispensing system. However, individual bottles (but not the one-month initiation pack) of Alunbrig could be added to an automated dispensing carousel or a robotic storage and retrieval solution where medications are stored in the manufacturer's original packaging.				
Pharmacy Order Processing and Verification					
Are calculations required when processing or verifying this medication (e.g., weight-based dose calculations)? • Are calculations performed manually by a pharmacist/pharmacy technician or electronically by an electronic workflow system or electronic health record (EHR)? • Should calculations be documented within the dispensing software or other system?	No[1-3]				
What are the approved indications and populations for this medication?	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.[1-3]	**Note:** If treatment is interrupted for 14 days or longer for reasons other than adverse reactions, dosing should be altered. Refer to the package insert for details.[1]			
Are there boxed warnings or contraindications?	No[1-3]				
Are there any immunization considerations?	No[1-3]				
What is the billing unit/quantity?	Billing unit is "each." 1 tablet = 1 "each"[3]				
Preparation and Dispensing					
Is this medication "ready to dispense" or does it require product preparation? • If so, what are the required preparation steps?	Yes – Ready to dispense.[1]				
Are additional supplies needed when dispensing (e.g., needle, syringe, alcohol swabs, sharps container, oral syringe)?	No[1-3]				
Administration and Disposal					
Can this medication be split, crushed, etc.?	No – Tablets should be swallowed whole. Do not crush or chew.[1-3]				
Is this medication "ready to administer" or does it require product preparation by the patient/caregiver or provider administering the medication? • If so, what are the required preparation steps?	Yes – Ready to administer.[1-3]				
Are there special disposal instructions (e.g., hazardous or sharps medication)?	Yes – Potentially hazardous disposal. Avoid release to the environment.[1-3,10,11] **Pharmacy to establish and define additional disposal processes and training procedures if needed.**				
Shipping and Delivery					
What are the temperature excursions allowed by the manufacturer?	Temperature excursions are permitted between 15°C to 30°C (59°F to 86°F).[1] Per an conversation with a representative from Takeda Oncology (Aug 2024), if a specific excursion occurs, pharmacies should contact the manufacturer directly for additional information.				
Is this medication shipped to the patient or to the provider for administration?	Patient[1]				

Resources

1. Alunbrig [package insert]. Lexington, MA: Takeda Pharmaceuticals America; 2022.
2. Brigatinib. AHFS Clinical Drug Information. American Society of Health-System Pharmacists. Bethesda, MD; 2024. Accessed August 15, 2024. https://ahfsdruginformation.com/ahfs-clinical-drug-information/
3. Brigatinib. Lexi-Drugs. UpToDate Lexidrug. UpToDate, Inc. Waltham, MA. Accessed August 26, 2024. https://online.lexi.com
4. US Department of Health and Human Services. Approved risk evaluation and mitigation strategies (REMS). Silver Spring, MD: US Food and Drug Administration; 2021. Accessed August 15, 2024. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
5. Centers for Disease Control and Prevention (CDC). Hazardous drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020; Procedures; and Risk Management Information. Fed Regist. 2020;85(85):25439-25451.
6. Institute for Safe Medication Practices. ISMP List of High-Alert Medications in Community/Ambulatory Care Settings. Horsham, PA: Institute for Safe Medication Practices (ISMP); 2021. Accessed August 15, 2024. https://home.ecri.org/blogs/ismp-resources/high-alert-medications-in-community-ambulatory-care-settings
7. Institute for Safe Medication Practices. ISMP List of Confused Drug Names. Horsham, PA: Institute for Safe Medication Practices (ISMP); 2023. Accessed August 15, 2024. https://home.ecri.org/blogs/ismp-resources/list-of-confused-drug-names
8. Institute for Safe Medication Practices. FDA and ISMP Lists of Look-Alike Drug Names with Recommended (Mixed Case) Letters. Horsham, PA: Institute for Safe Medication Practices (ISMP); 2023. Accessed August 15, 2024. https://home.ecri.org/blogs/ismp-resources/look-alike-drug-names-with-recommended-tall-man-mixed-case-letters
9. Phonetic and orthographic computer analysis (POCA), public version 2.9. US Food and Drug Administration. Updated April 25, 2024. Accessed August 15, 2024. https://poca-public.fda.gov/name_search
10. DailyMed. Alunbrig- brigatinib tablet, film coated. Bethesda, MD: US National Library of Medicine; 2023. Accessed August 15, 2024. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0fe9ff20-d402-41f3-bc1e-7002ea7007db
11. Safety Data Sheet, Alunbrig tablets. Takeda Pharmaceuticals; 2021.
12. United States Pharmacopeia and National Formulary (USP 43-NF 38). USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Rockville, MD; 2020.