Public Testimony Registration

1 message

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Summary of Testimony: Public Comment for Arizona Medicaid - Brukinsa® (zanubrutinib) capsules Clinical Development Updates BRUKINSA (zanubrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.1 This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. In September 2021, The U.S. Food and Drug Administration (FDA) also approved Brukinsa for two additional indications: 1) Waldenström's Macroglobulinemia (WM): The FDA granted Brukinsa full approval for the treatment of adult patients with Waldenström's Macroglobulinemia (WM) on September 1, 2021. 1,2 2) Marginal Zone Lymphoma (MZL): The FDA approved Brukinsa for adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen on September 15, 2021. This indication is under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. 1,3 NCCN Inclusion: Mantle Cell Lymphoma: Zanubrutinib (Brukinsa) is included as a second-line therapy option for MCL in the NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®).4 This is a 2A recommendation consistent with other BTK inhibitors for this indication. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: The National Comprehensive Cancer Network® (NCCN®) has updated its NCCN Guidelines® for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 4.2021) to reflect the addition of zanubrutinib. Zanubrutinib was added as an option for CLL/SLL in the NCCN Guidelines.5 Regardless of del(17p)/TP53 mutational status, Zanubrutinib was added as a Second-line option for patients with intolerance or contraindication to other BTK inhibitors as a category 2A recommendation; Other recommended regimen. For patients with del(17p)/TP53 mutation, Zanubrutinib was added as a First-line option for patients with contraindication to other BTKi as a category 2A recommendation; Other recommended regimen.5 Waldenstrom Macroglobulinemia: The NCCN has updated its NCCN Guidelines for Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL - Version 1.2022) to include Zanubrutinib as a Preferred Regimen for both Primary Therapy (Category 1) and Therapy for Previously Treated WM/LPL (Category 1).6 Marginal Zone Lymphoma: The NCCN has updated its NCCN Guidelines for B-Cell Lymphomas (Version 5.2021) to reflect the addition of zanubrutinib for Marginal Zone Lymphomas.7 Zanibrutinib (Brukinsa) is also included as a Preferred Regimen (Category 2A) for second-line and subsequent therapy for MZL patients who have received at least one prior anti-CD20-mAB regimen in the NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®).7 Note: BRUKINSA is not FDA-approved for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma at this time. References: 1) BRUKINSA [package insert] San

Mateo, CA: BeiGene USA, Inc; September 2021. 2) BeiGene Press Release. BeiGene. https://ir.beigene.com/news-details/?id=802fb825-acb1-455d-b916-c95068817a9d 3) BeiGene Press Release. BeiGene. https://ir.beigene.com/news-details/?id=0d5b56bb-d6cd-4606-a9bd-f49e85bb113b 4) Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.4.2021. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 17, 2021. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 5) Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma V.4.2021. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 12, 2021. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 6) Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma V.1.2022. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed June 25, 2021. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 7) Adapted with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas. V5.2021. Accessed September 22, 2021. © 2021 National Comprehensive Cancer Network, Inc. All rights reserved. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
Drug/Product: Brukinsa® (zanubrutinib) capsules
Therapeutic Drug Class: Oncology, Oral - Hematologic
Testimony Oral?
Testimony Written? Yes

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