| ME-H | External Submission: Bristol-Myers Squibb Company request to review recent 3-year update data for Checkmate-067, randomized, double-blind trial that evaluated the combination of nivolumab plus ipilimumab or nivolumab monotherapy versus ipilimumab monotherapy in patients with previously untreated advanced melanoma. Based on a review of survival data from the CheckMate-067 trial presented in the peer-reviewed publication, the panel voted to change nivolumab/ipilimumab from category 2A to category 1 for first-line systemic treatment of metastatic or unresectable disease. References:  
- Grob JJ, Schadendorf D, Wagstaff J, et al. Regional Differences in Overall Survival (OS) in Patients With Advanced Melanoma (MEL) Who Received Nivolumab (NIVO) Combined With Ipilimumab (IPI) or NIVO Alone in a Phase 3 Trial (CheckMate 067). Oral Presentation at the 2017 European Society for Medical Oncology (ESMO) Annual Meeting September 8-12, 2017; Madrid, Spain.  
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<td>External Submission: Genentech, Inc request to consider data presented in an abstract and an oral presentation at ESMO 2017 on the use of vemurafenib for the adjuvant treatment of ( BRAF ) V600 mutation-positive melanoma. Based on a review of the data in the online abstract, the panel voted to not include vemurafenib as an adjuvant treatment option for ( BRAF ) V600 mutation-positive melanoma. Reference: ESMO 2017 abstract: Lewis K, Maio M, Demidov L, et al. BRIM8: a randomized, double-blind, placebo-controlled study of adjuvant vemurafenib in patients (pts) with completely resected BRAFV600+ melanoma at high risk for recurrence. Presented at the European Society for Medical Oncology 42nd Congress in Madrid, Spain; September 8-12, 2017. ESMO Oral presentation.</td>
<td>YES</td>
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| External Submission: Amgen, Inc request to review the recent peer-reviewed publications presenting data from a phase 1b trial and a phase II trial on the use of talimogene laherparepvec (T-VEC) in combination with checkpoint inhibitors. Based on a review of the data presented in the two peer-reviewed publications, the panel voted to not include T-VEC/checkpoint immunotherapy combination as a treatment option for unresectable stage IIIB-IV.  
- Chesney J, Puzanov I, Collichio F, et al. Randomized, Open-Label Phase II Study Evaluating the Efficacy and Safety of Talimogene Laherparepvec in Combination With Ipilimumab Versus Ipilimumab Alone in Patients With Advanced, Unresectable Melanoma. J Clin Oncol 2017;0:JCO2017737379. | YES | NO | ABSTAIN | ABSENT | 10 | 13 | 1 | 4 |