### NCCN Guidelines for Melanoma V.2.2016 –Follow-up on 11-16-15

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| Internal Request: Review the data for talimogene laherparepvec, the first FDA-approved oncolytic virus therapy, for the treatment of melanoma lesions in the skin and lymph nodes. | Based on review and discussion of the published data and FDA approved indication, panel consensus supported adding talimogene laherparepvec (T-VEC) intralesional injection to the Melanoma Guidelines in the following settings:  
1. Primary treatment option for patients with Stage III in-transit melanoma. Added as a category 1 recommendation. (ME-5)  
2. Treatment option for patients with recurrent melanoma that is local, satellite, and/or in-transit. Added as a category 1 recommendation. (ME-8)  
3. Treatment option for patients with unresectable nodal recurrence with or without limited systemic disease. (ME-9)  
4. Treatment option for selected patients with disseminated (unresectable) distant metastatic disease especially for Stage IV-M1a (ME-10)  
   - Prescribing information for T-VEC | YES | NO | ABSTAIN | ABSENT |
| External Request: Submission from Amgen Inc., requesting to add talimogene laherparepvec to pages ME-8, ME-9, ME-10 of the Guidelines. | 23 | 0 | 2 | 2 |
| Internal Request: Review the data for ipilimumab based on the expanded FDA indication for its use as adjuvant therapy for patients with stage III melanoma. | Based on review and discussion of the published data and FDA-approved indication, panel consensus supported adding high-dose ipilimumab to the Melanoma Guidelines in the following settings:  
1. Adjuvant treatment option for patients with Stage III sentinel node positive disease. Added as a category 2B recommendation. (ME-4)  
2. Adjuvant treatment option for patients with Stage III disease with clinically positive node(s). Added as a category 2B recommendation. (ME-4)  
3. Adjuvant treatment option for patients who have had a complete lymph node dissection and/or a complete resection of the nodal recurrence. Added as a category 2B recommendation. (ME-9)  
   - Prescribing information for ipilimumab | YES | NO | ABSTAIN | ABSENT |
| External Request: Submission from Bristol-Myers Squibb Company to consider including ipilimumab on page ME-4 for the adjuvant treatment of fully resected Stage III melanoma. | 18 | 6 | 1 | 2 |

20 | 3 | 1 | 3
Based on discussion and review of the published phase III trial data (see reference below) and FDA-approved indication, panel consensus supported adding vemurafenib/cobimetinib combination therapy to the Melanoma Guidelines in the following settings:

1. First-line treatment option for patients with BRAF mutated metastatic or unresectable disease. Added as a category 1 recommendation.
   ME-E 1 of 6
   a. List vemurafenib/cobimetinib combination therapy "preferred" over single agent therapy in this setting.

2. Second-line or subsequent therapy treatment option for patients with BRAF mutated metastatic or unresectable disease. (ME-E 1 of 6)
   a. List vemurafenib/cobimetinib combination therapy "preferred" over single agent therapy in this setting.

- Prescribing information for cobimetinib