**Supplementary material**

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| --- | --- | --- | --- | --- | --- | --- |
| **Title** | **Year** | **TA** | **Type** | **ERG** | **Pivotal trial** | **PH assumption violation for OS or PFS** |
| [Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer](https://www.nice.org.uk/guidance/ta620)(2) | 2020 | TA620 | STA | BMJ-TAG | Study19, SOLO-2 | Y |
| [Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer](https://www.nice.org.uk/guidance/ta619)(6) | 2020 | TA619 | STA | LRiG | PALOMA3 | Y |
| [Lenalidomide with rituximab for previously treated follicular lymphoma](https://www.nice.org.uk/guidance/ta627)(7) | 2020 | TA627 | STA | KSR | AUGMENT | Y |
| [Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab](https://www.nice.org.uk/guidance/ta629)(8) | 2020 | TA629 (TA472) | CDF | ScHARR-TAG | GADOLIN | Y |
| [Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer](https://www.nice.org.uk/guidance/ta632)(9) | 2020 | TA632 | STA | KSR | KATHERINE | Y |
| [Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer](https://www.nice.org.uk/guidance/ta639)(10) | 2020 | TA639 | STA | LRiG | IMPASSION130 | N |
| [Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer](https://www.nice.org.uk/guidance/ta638)(11) | 2020 | TA638 | STA | KSR | IMPOWER133 | Y |
| [Gilteritinib for treating relapsed or refractory acute myeloid leukaemia](https://www.nice.org.uk/guidance/ta642)(12) | 2020 | TA642 | STA | ScHARR-TAG | ADMIRAL | N |
| [Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma](https://www.nice.org.uk/guidance/ta641)(13) | 2020 | TA641 | STA | KSR | ECHELON2 | Y |
| [Avelumab with axitinib for untreated advanced renal cell carcinoma](https://www.nice.org.uk/guidance/ta645)(14) | 2020 | TA645 | STA | LRiG | JAVELIN RENAL 101 | N |
| [Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma](https://www.nice.org.uk/guidance/ta649)(15) | 2020 | TA649 | STA | KSR | GO29365 | N |
| [Pembrolizumab with axitinib for untreated advanced renal cell carcinoma](https://www.nice.org.uk/guidance/ta650)(16) | 2020 | TA650 | STA | SHTAC | KEYNOTE426 | Y |
| [Osimertinib for treating EGFR T790M mutation-positive advanced non-small-cell lung cancer](https://www.nice.org.uk/guidance/ta653)(17) | 2020 | TA653 (TA416) | CDF | LRiG | AURA3 | N |
| [Nivolumab for advanced squamous non-small-cell lung cancer after chemotherapy](https://www.nice.org.uk/guidance/ta655)(4) | 2020 | TA655 (TA483) | CDF | LRiG | CHECKMATE 017 | Y |
| [Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma](https://www.nice.org.uk/guidance/ta658)(18) | 2020 | TA658 | STA | ScHARR-TAG | ICARIA MM | N |
| [Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma](https://www.nice.org.uk/guidance/ta661)(19) | 2020 | TA661 | STA | LRiG | KEYNOTE048 | Y |
| [Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia](https://www.nice.org.uk/guidance/ta663)(20) | 2020 | TA663 | STA | Warwick Evidence | CLL14 | Y |
| [Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma](https://www.nice.org.uk/guidance/ta666)(21) | 2020 | TA666 | STA | ScHARR-TAG | IMBRAVE | Y |
| [Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer](https://www.nice.org.uk/guidance/ta668)(1) | 2021 | TA668 | STA | Warwick Evidence | BEACON-CRC | Y |
| [Brigatinib for ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor](https://www.nice.org.uk/guidance/ta670)(22) | 2021 | TA670 | STA | LRiG | ALTA-1L | Y |
| [Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy](https://www.nice.org.uk/guidance/ta673)(23) | 2021 | TA673 | STA | BMJ-TAG | PRIMA | Y |
| [Lenalidomide maintenance treatment after an autologous stem cell transplant for newly diagnosed multiple myeloma](https://www.nice.org.uk/guidance/ta680)(24) | 2021 | TA680 | STA | PENTAG | MYELOMA XI | N |
| [Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer](https://www.nice.org.uk/guidance/ta683)(25) | 2021 | TA683 (TA557) | CDF | PENTAG | KEYNOTE189 | Y |
| [Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease](https://www.nice.org.uk/guidance/ta684)(26) | 2021 | TA684 (TA558) | CDF | BMJ-TAG | CHECKMATE 238 | N |
| [Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy](https://www.nice.org.uk/guidance/ta687)(27) | 2021 | TA687 (TA593) | CDF | BMJ-TAG | MONALEESA 3 | N |
| [Acalabrutinib for treating chronic lymphocytic leukaemia](https://www.nice.org.uk/guidance/ta689)(28) | 2021 | TA689 | STA | ScHARR-TAG | ELEVATE-TN | Y |
| [Carfilzomib with dexamethasone and lenalidomide for previously treated multiple myeloma](https://www.nice.org.uk/guidance/ta695)(29) | 2021 | TA695 | STA | BMJ-TAG | ASPIRE | N |
| [Olaparib plus bevacizumab for maintenance treatment of advanced ovarian, fallopian tube or primary peritoneal cancer](https://www.nice.org.uk/guidance/ta693)(30) | 2021 | TA693 | STA | BMJ-TAG | PAOLA-1 | N |
| [Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy](https://www.nice.org.uk/guidance/ta692)(31) | 2021 | TA692 (TA519) | CDF | Warwick Evidence | Keynote 045 | Y |
| [Atezolizumab monotherapy for untreated advanced non-small-cell lung cancer](https://www.nice.org.uk/guidance/ta705)(32) | 2021 | TA705 | STA | HERU/HSRU | IMPOWER-110 | Y |
| [Nivolumab for previously treated unresectable advanced or recurrent oesophageal cancer](https://www.nice.org.uk/guidance/ta707)(33) | 2021 | TA707 | STA | PENTAG | ATTRACTION-3 | Y |
| [Pembrolizumab for untreated metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency](https://www.nice.org.uk/guidance/ta709)(34) | 2021 | TA709 | STA | BMJ-TAG | KEYNOTE-177 | Y |
| [Nivolumab for advanced non-squamous non-small-cell lung cancer after chemotherapy](https://www.nice.org.uk/guidance/ta713)(35) | 2021 | TA713 (TA484) | CDF | LRiG | CHECKMATE 057 | Y |
| [Nivolumab with ipilimumab and chemotherapy for untreated metastatic non-small-cell lung cancer](https://www.nice.org.uk/guidance/ta724)(36) | 2021 | TA724 | STA | CRD/CHE | CHECKMATE 9LA | Y |
| [Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy](https://www.nice.org.uk/guidance/ta725)(37) | 2021 | TA725 (TA579) | CDF | BMJ-TAG | Monarch 2 | N |
| [Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer](https://www.nice.org.uk/guidance/ta737)(38) | 2021 | TA737 | STA | PENTAG | KEYNOTE-590 | Y |
| [Nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy](https://www.nice.org.uk/guidance/ta736)(39) | 2021 | TA736 (TA490) | CDF | KSR | CHECKMATE 141 | Y |
| [Atezolizumab for untreated PD-L1-positive advanced urothelial cancer when cisplatin is unsuitable](https://www.nice.org.uk/guidance/ta739)(40) | 2021 | TA739 (TA492) | CDF | SHTAC | IMvigor130 | Y |
| [Nivolumab for adjuvant treatment of resected oesophageal or gastro-oesophageal junction cancer](https://www.nice.org.uk/guidance/ta746)(41) | 2021 | TA746 | STA | ScHARR-TAG | CHECKMATE 577 | Y |
| [Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome](https://www.nice.org.uk/guidance/ta754)(42) | 2021 | TA754 | STA | KSR | MAVORIC | Y |

***Supplementary Table 1: Technology appraisals included in the review****. References included at end of supplement. Note for CDF reviews the original appraisal is included in parenthesis. TA=Technology appraisal; ERG=Evidence Review Group; PH=Proportional Hazard; STA=Single Technology Appraisal; CDF= Cancer Drugs Fund review; PENTAG=Peninsula Technology Assessment Group (University of Exeter); ScHARR-TAG=School of Health and Related Research Technology Assessment Group (University of Sheffield); BMJ-TAG=British Medical Journal Technology Assessment Group; LRiG=Liverpool Reviews and Implementation Group (University of Liverpool); SHTAC=Southampton Health Technology Assessment Centre (University of Southampton); KSR=Kleijnen Systematic Reviews; HERU/HSRU=Health Economics Research Unit and Health Services Research Unit (University of Aberdeen); CRD/CHE= Centre for Reviews and Dissemination (CRD) and Centre for Health Economics (CHE) (University of York)*

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| --- | --- |
| **Criterion** | **Response** |
| *Regarding PH testing:* |
| PH testing method used | Log-cumulative hazard plotSchoenfeld residualOther |
| Company and ERG agree on PH testing method?  | Yes/No |
| Company and ERG agree on PH testing outcome? | Yes/No |
| Presence of NPH for OS | Yes/No |
| Presence of NPH for PFS | Yes/No |
| *When PH assumption violated:* |
| Outcome measures reported in company submission/ERG report | Hazard ratioLog-rankMedianLandmark/percentileRMSTOther |
| Use of HR critiqued in company submission | Yes/No |
| Use of HR critiqued in ERG report | Yes/No |
| NPH discussed in FAD | Yes/No |
| Outcome measures reported to support clinical effectiveness conclusions in committee discussion (FAD) | Hazard ratioLog-rankMedianLandmark/percentileRMSTOther |

***Supplementary Table 2: Data collection form****. Generated inductively after initial review of the documents for each appraisal.*

*“The assumption of proportional hazards (PHs) has been shown not to hold for several outcomes…therefore the HR, CI and associated p-value for these analyses are at best challenging to interpret, potentially misleading and should be interpreted with caution” TA620*

*“It is unlikely that the proportional hazards (PH) assumption holds for the PFS analyses. Therefore, all HRs for PFS presented from the PALOMA-3 trial have no meaningful interpretation without the assumption of PH” TA619*

*“The ERG is disappointed that the company has presented hazard ratio results for PFS data when the assumption of proportional hazards has been violated and has not provided any rationale to explain why alternative approaches were not considered” TA483/TA655*

*“The company does not present an analysis of whether the hazard ratio, which assumes proportionality of the hazard rates between the two trial arms, is a suitable outcome when reporting results of PFS. In the cost‐effectiveness section, the company concludes that proportionality is not held and this would suggest that the estimate of the hazard ratio is not an accurate representation of the benefit” TA663*

*“The assumption of proportional hazard was not appropriate, suggesting that the hazard ratios may be unreliable” TA668*

*“The company concludes that the relative hazards are likely to vary over time and the assumption of proportional hazards is unlikely to hold…the ERG therefore emphasizes that the HR with accompanying 95% confidence interval (CI) is difficult to interpret and potentially misleading” TA673*

*“Hazard ratios may not appropriately summarise relative treatment effects given that the two treatment curves crossed, suggesting a violation of the proportional hazards assumption” TA707*

*“The assumption of PH is violated for both OS and PFS data for CheckMate 057. Consequently, it is inappropriate to summarise these data by using HRs and 95% confidence intervals (CI) estimated by a Cox PH model. For this reason, the ERG considers that HRs ought to be interpreted with caution” TA484/TA713*

***Supplementary Box 1:*** *Examples of ERG comments regarding reporting of hazard ratios in pivotal trials where the proportional hazards assumption is violated*

**Supplementary References**

1. National Institute for Health and Care Excellence (NICE). Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer. Technology appraisal guidance [TA668] [Internet]. NICE website. 2021. Available from: https://www.nice.org.uk/guidance/ta668

2. National Institute for Health and Care Excellence (NICE). Olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian tube or peritoneal cancer. Technology appraisal guidance [TA620] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta620

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8. National Institute for Health and Care Excellence (NICE). Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab. Technology appraisal guidance [TA629] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta629

9. National Institute for Health and Care Excellence (NICE). Trastuzumab emtansine for adjuvant treatment of HER2-positive early breast cancer. Technology appraisal guidance [TA632] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta632

10. National Institute for Health and Care Excellence (NICE). Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer. Technology appraisal guidance [TA639] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta639

11. National Institute for Health and Care Excellence (NICE). Atezolizumab with carboplatin and etoposide for untreated extensive-stage small-cell lung cancer. Technology appraisal guidance [TA638] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta638

12. National Institute for Health and Care Excellence (NICE). Gilteritinib for treating relapsed or refractory acute myeloid leukaemia. Technology appraisal guidance [TA642] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta642

13. National Institute for Health and Care Excellence (NICE). Brentuximab vedotin in combination for untreated systemic anaplastic large cell lymphoma. Technology appraisal guidance [TA641] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta641

14. National Institute for Health and Care Excellence (NICE). Avelumab with axitinib for untreated advanced renal cell carcinoma. Technology appraisal guidance [TA645] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta645

15. National Institute for Health and Care Excellence (NICE). Polatuzumab vedotin with rituximab and bendamustine for treating relapsed or refractory diffuse large B-cell lymphoma. Technology appraisal guidance [TA649] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta649

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18. National Institute for Health and Care Excellence (NICE). Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma. Technology appraisal guidance [TA658] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta658

19. National Institute for Health and Care Excellence (NICE). Pembrolizumab for untreated metastatic or unresectable recurrent head and neck squamous cell carcinoma. Technology appraisal guidance [TA661] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta661

20. National Institute for Health and Care Excellence (NICE). Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia. Technology appraisal guidance [TA663] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta663

21. National Institute for Health and Care Excellence (NICE). Atezolizumab with bevacizumab for treating advanced or unresectable hepatocellular carcinoma. Technology appraisal guidance [TA666] [Internet]. NICE website. 2020. Available from: https://www.nice.org.uk/guidance/ta666

22. National Institute for Health and Care Excellence (NICE). Brigatinib for ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor Technology appraisal guidance [TA670] [Internet]. NICE website. 2021. Available from: https://www.nice.org.uk/guidance/ta670

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