NICE National Institute for Health and Care Excellence

NICE guidance

Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer

Technology appraisal guidance
Published: 10 January 2024

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Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Durvalumab plus gemcitabine and cisplatin is recommended, within its marketing authorisation, as an option for treating locally advanced, unresectable, or metastatic biliary tract cancer in adults. It is only recommended if the company provides durvalumab according to the commercial arrangement.

Why the committee made these recommendations

Limited treatments options are available for unresectable or advanced biliary tract cancer, including cancer which reoccurs after surgery. Standard treatment includes chemotherapy with gemcitabine and cisplatin.

Clinical trial evidence shows that, compared with standard treatment, durvalumab plus gemcitabine and cisplatin increases how long people have before their condition gets worse and how long they live.

The cost-effectiveness estimates are uncertain. When considering the condition's severity, and its effect on quality and length of life, the most likely estimates are within the range that NICE considers an acceptable use of NHS resources. So, durvalumab plus gemcitabine and cisplatin is recommended.

2 Information about durvalumab plus gemcitabine and cisplatin

Marketing authorisation indication

2.1 Durvalumab (Imfinzi, AstraZeneca) in combination with gemcitabine and cisplatin is indicated for 'the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for durvalumab.

Price

2.3 The list price of durvalumab is £2,466 for a 500 mg per 10 ml vial (excluding VAT; BNF online, accessed October 2023).

2.4 The company has a commercial arrangement. This makes durvalumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Committee discussion

The evaluation committee considered evidence submitted by AstraZeneca, a review of this submission by the external assessment group (EAG), and responses from stakeholders. See the committee papers for full details of the evidence.

Clinical need

3.1 Biliary tract cancer includes bile duct cancer (cholangiocarcinoma), gallbladder cancer and ampullary cancer (distal extrahepatic cholangiocarcinoma). The committee noted that ampullary cancer which arises from the pancreas or small bowel was not within the scope of the appraisal. The patient experts described how biliary tract cancer is poorly understood because it affects a small number of people and symptoms are often misdiagnosed for other conditions. This means that most cases of biliary tract cancer are diagnosed at a late stage when the cancer is usually inoperable. One patient expert described how being diagnosed with advanced cholangiocarcinoma and the potential prospect of only living for a few weeks had a significant emotional effect on them and their family. They explained that while biliary tract cancer is more common in older people, it can also affect younger people as they had been diagnosed at the age of 44. The patient expert described how they had surgery to remove part of their liver followed by 6 months of adjuvant chemotherapy, which made them feel quite unwell at times. They explained that that the risk of cancer recurring after surgery is very high, and this remains a constant worry for them and their family. The patient experts highlighted that few first-line treatment options are available for unresectable or advanced biliary tract cancer and that chemotherapy (gemcitabine plus cisplatin) has remained the standard of care for over a decade in people who are eligible for treatment. Patient and clinical experts explained that the prognosis and quality of life with current chemotherapy is poor and that more treatment options are urgently needed. The committee noted that durvalumab (plus gemcitabine and cisplatin) is the first immunotherapy to be licensed as a first-line treatment for unresectable or advanced biliary tract cancer. It understood that molecular testing is usually not needed to start first-line treatment, so durvalumab can be given to all eligible people. The committee understood the substantial psychological, social and physical impact biliary tract

cancer has on people and their carers and families. It recognised that there is an unmet need for people with unresectable or advanced biliary tract cancer, and that the population eligible for treatment is estimated to be small. The committee concluded that people with the condition and their clinicians would welcome durvalumab plus gemcitabine and cisplatin as a treatment option.

Comparators

3.2 Surgery remains the curative intent treatment option leading to long-term survival for people diagnosed with resectable biliary tract cancer. Most people are diagnosed with unresectable locally advanced or metastatic biliary tract cancer. The committee discussed the company's positioning of durvalumab plus gemcitabine and cisplatin as a first-line treatment option for unresectable or advanced biliary tract cancer, including cancer which reoccurs after surgery with curative intent. The final scope for the appraisal included established clinical management without durvalumab. This included gemcitabine plus cisplatin, gemcitabine plus oxaliplatin (for people with poor kidney function) and gemcitabine, fluorouracil or capecitabine alone (for people who are frail). The company considered gemcitabine plus cisplatin to be the most suitable comparator. This was because it considered that people with poor kidney function or who are frail would not be eligible for treatment with cisplatin, so durvalumab plus gemcitabine and cisplatin would not be suitable for them. The clinical experts confirmed that most people would have gemcitabine plus cisplatin as a first-line treatment for unresectable or advanced biliary tract cancer. So, the committee concluded that gemcitabine plus cisplatin was the most relevant comparator to durvalumab plus gemcitabine and cisplatin.

Clinical effectiveness

TOPAZ-1 trial

3.3 The clinical evidence came from TOPAZ-1 which is an ongoing phase 3, double blind, randomised controlled trial. In this trial, durvalumab plus gemcitabine and cisplatin was compared with placebo plus gemcitabine and cisplatin. People in

the trial had durvalumab plus gemcitabine and cisplatin or placebo plus gemcitabine and cisplatin every 3 weeks (up to 8 cycles) followed by durvalumab or placebo monotherapy every 4 weeks until their cancer progressed. The population included adults with previously untreated unresectable advanced or metastatic biliary tract cancer, or whose cancer had reoccurred more than 6 months after surgery or completion of adjuvant therapy. The committee understood that people with ampullary cancer were excluded from the trial to decrease heterogeneity, because the genetic profile of ampullary cancer differs from other biliary tract cancer subtypes. There were 341 people in the intervention group and 344 people in the comparator group. The company reported data from the trial's latest data cut (February 2022, for overall survival with a median follow-up of around 22 months, data maturity 76.9%) and second interim analysis (August 2021, for progression free survival with a median follow up of around 16 months, data maturity 83.6%). In the intention-to-treat (ITT) population, durvalumab plus gemcitabine and cisplatin increased the median overall survival from 11.3 months to 12.9 months (hazard ratio 0.76; 95% confidence interval 0.64 to 0.91, no p value reported) compared with placebo plus gemcitabine and cisplatin. Durvalumab plus gemcitabine and cisplatin also increased the median progression-free survival from 5.7 months to 7.2 months (hazard ratio 0.75; 95% confidence interval 0.63 to 0.89, p value 0.001) compared with placebo plus gemcitabine and cisplatin. The company and EAG agreed that the proportional hazard assumption did not hold for overall survival and progression free survival. Because of this, the EAG considered the piecewise hazard ratios for distinct time periods to be more informative than the hazard ratios provided for the whole trial period. The committee noted that the piecewise hazard ratios suggested that the treatment benefit of durvalumab plus gemcitabine and cisplatin on overall survival and progression-free survival was seen several months after randomisation. It understood that this was likely because of how durvalumab works as an immunotherapy. The committee welcomed the mature trial data from TOPAZ-1 and concluded that durvalumab plus gemcitabine and cisplatin improves overall survival and progression-free survival compared with gemcitabine plus cisplatin.

Generalisability of TOPAZ-1

3.4 TOPAZ-1 included 105 sites with 8 UK treatment centres (n=47). Aproximately

half (54.6%) of people from TOPAZ-1 were recruited from treatment centres in Asia. The EAG noted that the treatment effect of durvalumab plus gemcitabine and cisplatin versus placebo plus gemcitabine and cisplatin on overall survival was numerically greater for certain subgroups. This included people of Asian ethnicity (when compared to people of other ethnicities) and people living in Asia (when compared to people living in other parts of the world). Clinical advice to the EAG was that this benefit may be because of the relatively high incidence of hepatitis B in Asia, which may be linked to better responses to durvalumab plus gemcitabine and cisplatin. In response to technical engagement, the company gave an analysis of overall survival in people with and without viral hepatitis. The committee noted that the results of the analysis suggested a consistent overall survival benefit across these groups. The clinical expert explained that the only likely difference for people with hepatitis is that they may be diagnosed at an earlier stage. The company also gave results from an exploratory interaction test for region and treatment which suggested a consistent overall survival effect across people living in Asia and other parts of the world. The company explained that the subgroup analyses were not powered to detect statistically significant differences and that no adjustments were made for multiple testing. The committee acknowledged the limitations around the company's subgroup analyses. It noted that the results for people of Asian ethnicity and for people living in Asia were statistically significant (based on the confidence intervals around the hazard ratios) and implied a larger treatment benefit compared to people of other ethnicities and from other parts of the world, respectively. It discussed the EAG's critique that people in the trial were younger (median age 64 years) than those presenting with biliary tract cancer in the NHS (average age around 70 years). The committee also recalled the patient expert testimony describing how biliary tract cancer can affect younger people (see section 3.1), but it considered that in most cases it would be diagnosed in older people. The clinical experts explained that age does not impact response to treatment, its effectiveness or eligibility for subsequent treatments (which depend on a person's fitness). The committee noted that TOPAZ-1 included people with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. It recalled that the company had considered that people who are frail (with an ECOG performance status greater than 1) would not be suitable for treatment with cisplatin (see section 3.2). Clinical advice to the EAG was that some people with an ECOG performance status of 2 are suitable for treatment with chemotherapy and may be offered gemcitabine plus cisplatin. The clinical experts

explained that in people for whom chemotherapy is suitable, 75% have an ECOG performance status of 0 or 1 and 25% have an ECOG performance status of 2. The clinical lead for the Cancer Drugs Fund confirmed that if durvalumab was recommended, it would only be available to people with an ECOG performance status of 0 or 1 based on the clinical trial data. The committee understood that the clinical experts considered participants in the trial to be representative of people with unresectable or advanced biliary tract cancer treated in the NHS. The committee considered that there was some uncertainty as to whether the TOPAZ-1 population results were generalisable to NHS clinical practice because of the age of the trial population and differences in the magnitude of treatment benefit between certain subgroups. It concluded that it was not possible to quantify this uncertainty in the cost-effectiveness estimates, but that the results from TOPAZ-1 were appropriate for decision-making.

Economic model

Company's modelling approach

3.5 The company gave a partitioned survival model with 3 mutually exclusive health states: progression-free, progressed disease and death. The modelled intervention and comparator reflected TOPAZ-1. The model perspective on costs was that of the NHS and Personal Social Services and the cycle length was 1 week. A half-cycle correction was applied to all costs and outcomes, except for first-line drug and administration costs during the first cycle. The time horizon was 20 years, and costs and outcomes were discounted at a rate of 3.5% per year. The EAG considered that the model structure was appropriate for modelling the decision problem. The committee concluded that the company's model was acceptable for decision making.

Modelling overall survival for durvalumab plus gemcitabine and cisplatin

3.6 Both the company and EAG considered that several parametric distributions statistically fitted the overall survival data from TOPAZ-1 equally well and were

clinically plausible. The company selected the spline 1 knot odds distribution to model overall survival in its base case for people on durvalumab plus gemcitabine and cisplatin. The EAG also selected the spline 1 knot odds distribution for its base case but considered that the gamma distribution was a clinically and statistically plausible alternative. It highlighted that overall survival beyond TOPAZ-1 was uncertain with either extrapolation, but that the choice of distribution had a large effect on the incremental cost-effectiveness ratio (ICER). In response to technical engagement, the company explained that selecting the gamma distribution for the durvalumab plus gemcitabine and cisplatin arm suggested no additional long-term overall survival benefit compared with the gemcitabine plus cisplatin arm. It considered that this was not plausible because durvalumab is an immunotherapy so it would take time to produce an effective immune response that could be translated into an observable and durable clinical response. The clinical expert explained that only a small number of people would have a long-term survival benefit with durvalumab treatment because it works differently to gemcitabine and cisplatin. They explained that it was not possible to define this subgroup of people who would benefit from treatment with durvalumab because a biomarker was not yet available. The committee understood that people would usually stop treatment with gemcitabine plus cisplatin after 6 months (8 cycles every 3 weeks) and then remain on durvalumab monotherapy until their cancer progresses or they experience unacceptable toxicity with treatment. The clinical expert described how durvalumab is usually much better tolerated than gemcitabine and cisplatin which usually have more toxic side effects. They explained that in people who have a prolonged survival benefit, treatment with durvalumab alone would have little effect on their quality of life. The committee discussed whether the hazards for overall survival between the durvalumab plus gemcitabine and cisplatin arm and the gemcitabine plus cisplatin arm would differ because of how durvalumab works. The clinical expert explained that the risk of death would likely remain high for people on gemcitabine plus cisplatin, but that with the addition of durvalumab this risk would likely plateau, reflecting the small number of people whose condition is controlled after treatment. The company explained that the hazard of the spline 1 knot odds distribution closely fitted the TOPAZ-1 hazard by capturing the long-term survival benefit that a small number of people would likely have with durvalumab. The committee noted that clinical experts had found it challenging to comment on the clinical plausibility of overall survival extrapolations because of their limited experience with durvalumab plus gemcitabine and cisplatin in

clinical practice. It concluded that overall survival with durvalumab plus gemcitabine and cisplatin beyond TOPAZ-1 was highly uncertain, but that the company's and EAG's approach of selecting the spline 1 knot odds distribution was reasonable.

Modelling progression-free survival for durvalumab plus gemcitabine and cisplatin

3.7 The company selected the spline 1 knot odds distribution to model progression free survival for people on durvalumab plus gemcitabine and cisplatin. The EAG considered that the distribution selected by the company had a relatively poor statistical fit to the TOPAZ-1 data. So, it preferred the spline 3 knot hazard distribution instead because it considered this provided a better fit and the progression-free survival estimates matched the trial data most closely at 6 and 12 months. The company explained that most of its clinical experts considered that the progression-free survival rate at 2 years would be around 5% which most closely aligned with the estimate using the spline 1 knot odds distribution. It further considered that the spline 3 knot hazard distribution risked overfitting the TOPAZ-1 data. The EAG explained that the choice of extrapolation had a smaller effect on the ICER (compared with overall survival) because the progression-free survival data from TOPAZ-1 was more mature in that most people's condition had progressed at the time of the data cut (see section 3.3). The committee noted that the clinical experts had also found it challenging to comment on the clinical plausibility of progression-free survival extrapolations because of their limited experience with durvalumab plus gemcitabine and cisplatin in clinical practice. It concluded that progression-free survival beyond TOPAZ-1 for the durvalumab plus gemcitabine and cisplatin arm was highly uncertain. The committee further concluded that the EAG's approach of selecting the spline 3 knot hazard distribution to model progression-free survival was more appropriate than the company's because it had a better statistical fit to the data from TOPAZ-1.

Modelling progression-free survival for gemcitabine plus cisplatin

3.8 The company selected the spline 1 knot normal distribution to model progression-

free survival for people on gemcitabine plus cisplatin in its base case. The company stated that this distribution generated a clinically plausible progression-free survival rate at 2 years and closely matched the TOPAZ-1 data at 6 months. The EAG considered that compared with the TOPAZ-1 data, all the parametric distributions considered by the company overestimated the progression-free survival rate at 12 months. It preferred the spline 3 knot odds distribution because it considered that it had the best statistical fit to TOPAZ-1 and generated progression-free survival estimates that most closely matched the data at 12 months. The committee noted that selecting the spline 3 knot odds distribution had a minimal effect on the ICER compared with the spline 1 knot normal distribution. The committee agreed with the EAG's approach and concluded that the spline 3 knot odds distribution was the most appropriate to model progression-free survival for the gemcitabine plus cisplatin arm.

Modelling treatment costs

3.9 The company modelled treatment costs using progression-free survival as a proxy for time to treatment discontinuation (TTD), despite TTD data being available from TOPAZ-1. The EAG considered that progression-free survival was not a good proxy for TTD for the durvalumab plus gemcitabine and cisplatin arm because the trial data suggested that TTD is always longer than progression free survival. So, it considered that using progression-free survival data would underestimate the true costs of treatment. The company's clinical experts considered that people with biliary tract cancer typically have gemcitabine plus cisplatin for a maximum of 6 months. For the gemcitabine plus cisplatin arm, the EAG considered that progression-free survival was a reasonable proxy for TTD as the trial data for progression free survival and TTD closely matched up to 6 months. The EAG explained that more accurate costs of treatment can be generated by fitting parametric distributions to TOPAZ-1 TTD trial data. The company explained that it preferred to use progression-free survival data to model treatment costs because this was more reflective of real-world treatment costs. It considered that if durvalumab was recommended, it would be given until the person's cancer progresses or they experience unacceptable toxicity with treatment, in line with its marketing authorisation. The clinical expert commented that progression-free survival might be an appropriate measure for treatment duration from a clinical perspective, but when considering treatment costs these

should be modelled based on TTD data. The committee discussed how in clinical practice some people may have treatment beyond their condition progressing. The clinical lead for the Cancer Drugs Fund highlighted that people who were clinically stable when their cancer initially progressed in TOPAZ-1 could continue to have study treatment at the discretion of the investigator and patient. This reflects the likely use of durvalumab in the NHS. For the durvalumab plus gemcitabine and cisplatin arm, the company presented a scenario analysis which used TTD to cost time on treatment. It selected the spline 1 knot odds distribution in this scenario to model TTD because the estimated proportion of people still on treatment at 2 years was similar to the company's modelled progression-free survival rate at 2 years. The committee noted that the EAG preferred the spline 3 knot hazard distribution because it had a better statistical fit and the estimated proportion of people remaining on treatment at 6 and 12 months most closely matched the TOPAZ-1 values. For the gemcitabine plus cisplatin arm, the company selected the spline 3 knot hazard distribution to model TTD. The committee noted that the EAG preferred the spline 2 knot odds distribution because the proportion of people remaining on treatment at 6 months most closely matched TOPAZ-1 data. The committee recognised that modelling treatment costs using TTD had a large effect on the ICER. It concluded that treatment costs should be modelled based on TTD from TOPAZ-1 and agreed with the EAG's preferred distributions for both arms.

Utility values

3.10 The company's model used health state utility values from TOPAZ-1. In the trial, health-related quality-of-life data was collected using the EuroQol 5-dimensions 5-level questionnaire (EQ-5D-5L) at baseline, every 3 weeks for the first 8 treatment cycles and then every 4 weeks until disease progression or death. After 16 cycles, assessments were done every other cycle. In line with the NICE reference case, the EQ-5D-5L responses were mapped to produce EQ-5D 3-level (EQ-5D-3L) utility values. The company used mixed models for repeated measures to estimate the statistical relationship between utilities and health state, and in the base case progression status was selected to model utilities. The EAG noted that the utility value for the progression-free health state (the company consider the value to be confidential so it cannot be reported here) was optimistic because it was close to the age-adjusted UK general population norm.

The committee understood that in the model, people on durvalumab plus gemcitabine and cisplatin would spend more time in the progression-free health state and so a higher utility value will increase the quality-adjusted life years (QALYs) associated with treatment. The EAG considered that the utility value for the progressed disease health state (the company consider the value to be confidential so it cannot be reported here) was more uncertain because it was estimated based on fewer observations from fewer people compared with the progression-free health state. The committee noted the EAG's critique that as the utility values were estimated using TOPAZ-1 data, it is appropriate to use them, but their use may favour durvalumab plus gemcitabine and cisplatin. The committee recognised this uncertainty but concluded that the utility values from the trial were appropriate for decision-making.

QALY weighting

3.11 In its submission, the company provided evidence that unresectable or advanced biliary tract cancer is a severe condition. The committee considered the severity of the condition (the future health lost by people living with the condition and having standard care in the NHS). The committee may apply a greater weight to QALYs (a severity modifier) if technologies are indicated for conditions with a high degree of severity. The company provided absolute and proportional QALY shortfall estimates in line with NICE's health technology evaluations manual. To inform the baseline characteristics in the QALY shortfall calculations, the company used the mean age and sex distribution from TOPAZ-1. The company used the total QALYs from the model for the gemcitabine plus cisplatin arm to inform the total expected QALYs for people with the condition on standard care. The company used population utility norms from Ara and Brazier (2010) and mortality estimates informed by the most recent Office for National Statistics life tables (2021) to inform the total expected QALYs for people without the condition. The company considered that based on the proportional shortfall result (0.928), a QALY weighting of 1.2 should apply. The EAG considered that the methods used by the company to estimate the severity modifier were appropriate. It recalculated the QALY shortfalls using its preferred assumptions and noted that the proportional shortfall still implied that a QALY weighting of 1.2 would apply. The EAG explained that the severity weighting did not change when different parametric distributions were used to extrapolate data beyond TOPAZ-1,

because the life expectancy for the population under consideration is short. The committee recalled the EAG's critique that people in the trial were younger than those presenting with biliary tract cancer in the NHS (average age around 70 years, see section 3.4). It considered that increasing the age up to 80 years in the QALY shortfall calculation would be unlikely to change the severity weight of 1.2. The committee recognised that this is a severe disease for the population under consideration. It concluded that a severity weight of 1.2 applied to the QALY gains was appropriate.

Cost-effectiveness estimates

Uncertainty in cost-effectiveness estimates

3.12 NICE's health technology evaluations manual notes that judgements about the acceptability of a technology as an effective use of NHS resources will take into account the degree of certainty around the ICER. The committee will be more cautious about recommending a technology if it is less certain about the ICERs presented. The exact ICERs are confidential and cannot be reported here because they include the confidential discount for durvalumab and a confidential discount for a subsequent treatment in the pathway. The company's base case ICERs including the severity weighting of 1.2, were below £30,000 per QALY gained. The EAG gave analyses which included minor corrections to the company base case and combined the committee's preferred modelling assumptions:

- Using the spline 1 knot odds to model overall survival for durvalumab plus gemcitabine and cisplatin (see section 3.6).
- Using the spline 3 knot hazard distribution to model progression free survival for durvalumab plus gemcitabine and cisplatin (see section 3.7).
- Using the spline 3 knot odds distribution to model progression free survival for gemcitabine plus cisplatin (see section 3.8).
- Parametric distribution fitted to TTD data (spline 3 knot hazard) to model treatment costs for durvalumab plus gemcitabine and cisplatin (see section 3.9).

- Parametric distribution fitted to TTD data (spline 2 knot odds) to model treatment costs for gemcitabine plus cisplatin (see section 3.9).

Using these preferred assumptions, including the severity weighting of 1.2, the committee's preferred ICERs for durvalumab plus gemcitabine and cisplatin compared with gemcitabine plus cisplatin were between £20,000 and £30,000 per QALY gained. The committee decided that a maximum threshold of £30,000 per QALY gained was acceptable, given the high level of unmet need. It noted that although there was uncertainty in the modelling, the most likely cost-effectiveness estimates were within the range that NICE considers to be an acceptable use of NHS resources. So, it recommended durvalumab plus gemcitabine and cisplatin as an option for people with unresectable or advanced biliary tract cancer.

Other factors

Equality

3.13 A stakeholder commented that liver cancer disproportionally affects people from deprived areas and that, if recommended, durvalumab plus gemcitabine and cisplatin should be accessible to all people irrespective of where they live. The committee agreed that access to treatments is an implementation issue that cannot be addressed by a technology appraisal recommendation. It concluded that there were no equality issues relevant to the recommendations.

Innovation

3.14 The committee recalled that durvalumab plus gemcitabine and cisplatin is the first immunotherapy to be approved as a first-line treatment for unresectable or advanced biliary tract cancer (see section 3.1). It considered if durvalumab plus gemcitabine and cisplatin was innovative. The committee did not identify any additional benefits of durvalumab plus gemcitabine and cisplatin not captured in the economic modelling. So, it concluded that all the additional benefits of durvalumab plus gemcitabine and cisplatin had already been considered.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.

4.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

4.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has unresectable or advanced biliary tract cancer and the doctor responsible for their care thinks that durvalumab plus gemcitabine and cisplatin is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee C.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each evaluation committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Professor Stephen O'Brien
Chair, technology appraisal committee C

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

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Accreditation