NHS

National Institute for Clinical Excellence

Guidance on the use of trastuzumab for the treatment of advanced breast cancer

1. Guidance

1.1 Trastuzumab in combination with paclitaxel (combination trastuzumab is currently only licensed for use with paclitaxel) is recommended as an option for people with tumours expressing human epidermal growth factor receptor 2 (HER2) scored at levels of 3+ who have not received chemotherapy for metastatic breast cancer and in whom anthracycline treatment is inappropriate.

1.2 Trastuzumab monotherapy is recommended as an option for people with tumours expressing HER2 scored at levels of 3+ who have received at least two chemotherapy regimens for metastatic breast cancer. Prior chemotherapy must have included at least an anthracycline and a taxane where these treatments are appropriate. It should also have included hormonal therapy in suitable oestrogen receptor positive patients.

1.3 HER2 levels should be scored using validated immunohistochemical techniques and in accordance with published guidelines. Laboratories offering tissue sample immunocytochemical or other predictive tests for therapy response should use validated standardised assay methods and participate in and demonstrate satisfactory performance in a recognised external quality assurance scheme.

This section (Section 1) constitutes the Institute's guidance on the use of trastuzumab for the treatment of advanced breast cancer. The remainder of the document is structured in the following way:

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Sefydliad Cenedlaethol dros Ragoriaeth Glinigol

Arweiniad ar ddefnyddio trastuzumab wrth drin canser datblygedig y fron

1 Arweiniad

1.1 Argymhellir trastuzumab mewn cyfuniad â paclitaxel (dim ond ar gyfer ei ddefnyddio ar y cyd â paclitaxel y mae trastuzumab cyfunadwy wedi ei drwyddedu ar hyn o bryd) fel dewis ar gyfer pobl sydd â thiwmorau sy'n dangos derbynnydd 2 ffactor tyfiant epidermaidd dynol (HER2) wedi'u sgorio ar lefelau 3+ nad ydynt wedi derbyn cemotherapi ar gyfer canser metastatig y fron a phan fo triniaeth anthracycline yn amhriodol ar eu cyfer.

1.2 Argymhellir monotherapi trastuzumab fel dewis ar gyfer pobl sydd â thiwmorau sy'n dangos HER2 wedi'u sgorio ar lefelau 3+ sydd wedi derbyn o leiaf 2 gyfres o gemotherapi ar gyfer canser metastatig y fron. Dylai cemotherapi blaenorol fod wedi cynnwys o leiaf un anthracycline a taxane pan fo'r triniaethau hyn yn briodol. Dylai hefyd fod wedi cynnwys therapi hormonaidd mewn cleifion sy'n sensitif i oestrogen.

1.3 Dylid sgorio lefelau HER2 drwy ddefnyddio technegau immunohistogemegol dilys yn unol â chanllawiau cyhoeddedig. Dylai labordai sy'n cynnig profion immunocytogemegol samplu meinwe neu brofion daroganol ar gyfer ymateb therapi ddefnyddio dulliau profi safonol dilys a chyfranogi mewn perfformiad boddhaol ac arddangos hynny mewn cynllun sicrwydd ansawdd allanol cydnabyddedig.

Mae'r adran hon (Adran 1) yn ymgorffori Arweiniad y Sefydliad ar ddefnyddio trastuzumab wrth drin canser datblygedig y fron. Strwythurir gweddill y ddogfen fel a ganlyn:

Arweiniad Arfarniad Technoleg Rhif 34

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