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Breast Cancer Diagnostic Approach

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Abstract: *According to European scientists, about 90% of newly diagnosed cancers occur in epithelial forms of cancer, among them, one of the most common is breast cancer (BC). In Western Europe, approximately 25% of breast cancers are detected in women under the age of 50. Breast cancer is less common in men and accounts for only 1% [5,8]. Mammographic screening conducted every two years in the age group from 50 to 69 years reduces the cancer mortality rate by 15%, but also increases the probability of hyperdiagnosis by 30% [4,8].*

Key words: *breast cancer, screening, diagnosis, treatment*

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Over the past twenty-plus years, breast cancer deaths in the United States and some developed European countries have been decreasing by 1-2% annually, thanks to early screening and continuous improvement of diagnosis and treatment [9]. Mortality from breast cancer in the Republic of Kazakhstan ranks first in the overall cancer structure – 11.6% (2011). Cancer screening, as part of the implementation of the "Program for the development of cancer care in the Republic of Kazakhstan for 2012-2016", has significantly improved the cancer situation. The incidence of breast cancer in 2012 was 23.5 / 100,000 and the mortality rate was 8.4 / 100,000. In general, the National Screening Program covers the following oncological diseases: breast cancer, prostate cancer, esophageal and gastric cancer, liver and colorectal cancer, and it is also planned to introduce an early lung cancer protocol [1,2,3].

Breast cancer diagnostics, with the participation of 24 leading Monitoring quality indicators, will allow you to justify the medical and economic costs of each service relative to the clinical outcome. Full version "Quality indicators in breast cancer care"can be found in the specified literature reference [9,27]. Experts ' efforts are aimed at achieving the final result by using routine measurements and evaluating available indicators, which will guarantee the quality of medical services provided with appropriate standards of diagnosis and treatment [9]. Annual mammographic screening and magnetic resonance imaging (MRI) of the breast are recommended for women with a "very high risk" of developing breast cancer: positive BRCA-1 or BRCA-2 mutations, as well as other gene predispositions that increase the risk of breast cancer; not tested carriers genetic mutation, in carriers of the first degree of kinship; hereditary breast cancer syndrome, when the total personal lifetime risk is more than 25%. Mammography and MRI screening, with less evidence, is recommended for women with a high marker risk, based on the results of biopsy (atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ) and after chest radiotherapy (under the age of 30 years or at least 8 previous years) [8]. ESMO experts recommend performing an annual breast MRI and mammogram to diagnose cancer for more than a year. favorable, preclinical stage, women with a family history of breast cancer, regardless of the proven carrier of the BRCA mutation. If BRCA carriage is confirmed by a test, preventive procedures are

recommended for patients [7,8]. The pathological diagnosis of breast cancer is based on a primary puncture biopsy obtained under ultrasound or stereotactic control. The pathomorphological conclusion should include: determination of histological type; histological maturity; immunohistochemical (IHC) assessment of the status of estrogen receptors (ER), using standard Allred methods or H-core; assessment of cancer aggressiveness by IHC assessment of progesterone receptors (PR) and HER2 expression. Routine cancer identification is aimed at determining the local-local spread of cancer, so it is not necessary for all patients to conduct comprehensive laboratory and radiological staging of cancer, since distant metastases are very rarely asymptomatic [7,9,10]. Additional tests, such as computed tomography (CT) of the chest, abdominal ultrasound or CT, and X-ray examination of the bones, are necessary for patients: with clinically positive results. axillary nodules; with a large tumor formation (≥5 cm); with clinical symptoms or laboratory data suggesting the presence of metastases [4,9]. A method of functional and anatomical characterization, such as positron emission tomography (PET) / CT, is necessary when conventional methods do not allow a definitive diagnosis to be made. The use of PET / CT for staging the local / regional spread of cancer is not advisable, due to the limited specificity compared to the "gold standard" of axillary staging of breast cancer: sentinel lymph node biopsy. an axillary node block (SLNB), which is recommended if axillary node involvement is not proven [5,8,13]. Routine methods for determining the amplification status of the HER2 gene are fluorescent, chromogenic and silver in situ hybridization of histological material of the primary tumor. The choice of a reliable method for determining the status of the HER2 gene is very important for preventing overdiagnosis and hypertreatment with anti-HER targeted agents. In case of ambiguous HER(2+) IHC results, analysis by one of the in situ hybridization methods is recommended [7, 8, 9, 15]. In case of negative ER results/PR and HER2 in the puncture trepan biopsy material, it is necessary to re-check the ER/PR of HER2 on surgical material after resection of the tumor [19]. Complete postoperative pathomorphological evaluation of the surgical preparation should be performed according to the pTNM system. The final pathological diagnosis should be made according to the Classification of the World Health Organization [14] with an analysis of the entire volume of the resected tumor. AD Status/PR and HER2 are the most reliable and effective predictor markers of the response to hormonal therapy. and anti-HER2 therapy. In addition, high ER expression may predict less benefit from chemotherapy [5,7,11]. A proliferation marker such as the Ki67 index may provide additional useful information about the aggressiveness of the process [7,8,13,21]. After neoadjuvant systemic treatment, cancer response to treatment and the amount of residual disease are important prognostic factors, but more convincing standardized biological markers are still needed. Currently, there are no universal guidelines for evaluating the response to neoadjuvant treatment. Although there are many published results of scientific studies devoted to the study of the molecular panel of predictors of response to breast cancer treatment [5,6,7,8]. The original edition of the National Policy on Circulating Cancer Cells (Health Net, Inc. 2012) recommended the standard definition of circulating cancer cells by the CellSearch system (Veridex) in the United States for the prognosis and control of treatment, including metastatic breast cancer [6]. The latest National Policy Statement on Circulating Cancer Cells (Health Net, Inc. 2014) recommends that further research be conducted to study circulating cancer cells in all their possible values and available research options. Although they note the great importance of circulating cancer cells in predicting the development of disease and survival in some forms of metastatic cancer. The authors of the publication warn that there are no proven definitive results in the literature indicating the possibility of changing therapy and improving the results of treatment based on circulating cancer cells. It is noted that the sensitivity of circulating cancer cells is relatively lower than that of some imaging methods. In addition, the authors of the document claim:, that there are no data confirming the high efficacy and clinical benefit of circulating cancer cells over other cancer biomarkers, and perhaps the results of the expected numerous ongoing clinical trials will allow us to determine the

clinical role and significance of circulating cancer cells in cancer treatment [6,28]. The importance of micro-metastatic dissemination and isolated circulating cancer cells for optimal management of the cancer process is a matter of ongoing research [5,6,21]. Determination of the predictive index – Nottingham The Prognostic Index (NPI), which depends on clinical parameters (tumor size, lymph node involvement, and the degree of histological maturity of cancer), will allow predicting the likelihood of recurrence and mortality from breast cancer [21,26]. The interpretation is presented in Table 2. You can calculate the index using the following program: NPI calculator-Primed.info or by the formula: NPI = [0,2 xS] + N + G, where S is the size of the indexed formation in cm; N is the number of lymph nodes involved: 0 =1, 1-3 = 2, >3 = 3 G is the degree of histological maturity of the tumor: GradeI =1, GradeII =2, GradeIII =3)Scale NPI 5 – year survival rate NPI prognosis >/=2.0 to></=2.4 93% Very good prognosis >2.4 to</=2.4 93% Very good prognosis ></=3.4 85% Good prognosis >3.4 to</=3.4 85% Good prognosis ></=5.4 70% Average prognosis >5.4 50% Poor prognosis The most important prognostic factors for early breast cancer are the expression of ER/PR, HER2 gene and proliferation marker, the number of regional lymph nodes involved.nodules, histological varian of the tumor, size, degree of histological maturity, and presence of peritumoral vascular invasion [5,7,8,9,21].

Surgical treatment tactics. Currently, about 60-80% of newly diagnosed cancers are subject to breast-preserving surgery, extensive local excision, and radiation therapy (RT). Although some patients still need a mastectomy due to the size of the tumor, the multifocality of the process, if negative surgical margins cannot be achieved after multiple resections, previous irradiation of the chest wall or chest, also due to other contraindications to RT or according to the patient's preference [29]. Tactics of preventive surgery for bilateral mastectomy in women with a "very high risk" of developing breast cancer, it reduces the risk of developing breast cancer by 90-95%. All women who need a mastectomy should have access to breast plastic surgery. Oncoplasty will allow achieving a better cosmetic result in patients with large breasts, with a less favorable tumor/breast size ratio, or from a cosmetic point of view, with difficult localization of the tumor [29,30]. In patients with ductal carcinoma in situ (non-invasive cancer), breast-preserving surgery is recommended if clean resection margins are achievable or mastectomy should be recommended [31].

Radiation therapy The extremely low rate of local cancer recurrence remains the main criterion for ensuring the quality of radiation therapy for cancer. ESMO experts determined the maximum allowable rate of local cancer recurrence: no more than 1% per year and no more than 10% in general after extensive excision of breast cancer and radiation therapy [4]. The results of studies indicate that further exposure to the axillary region is not required when there are micro-metastases up to 0.2-2.0 mm in the sentinel node. Patients with isolated cancer cells in the form of metastases breasts, and do not require further underarm procedures. The presence of macro-metastatic dissemination in the sentinel node requires mandatory axillary lymphodissection (clearance) as a standard of treatment [13]. Postoperative radiation therapy is recommended for patients who have organ-preserving surgery. Radiotherapy reduces the risk of further cancer progression by 50% and is an indicator of local control for patients with unfavorable risk factors [12]. Radical radiotherapy after organ-preserving surgery in patients with ductal carcinoma in situ reduces cancer recurrence [31]. Post-mastectomy RT is recommended for patients with four or more positive axillary nodes and/or a T3–T4 tumor, as well as for patients with one or three positive axillary lymph nodes, especially in the presence of additional risk factors [12,13,24,25]. Partial breast irradiation is an acceptable treatment option for patients older than 50 years with single-node, unifocal, node-negative, non-lobular breast cancer up to 3 cm in size, without extensive intra-ductal component or lymphovascular invasion [32]. Short fragmented regimens of 15-16 fragments with a single dose of 2.5-2.67 Gy have been confirmed in prospective clinical studies and are standardly recommended for the treatment of breast cancer [12,24,25].

Hyperthermia of cancerThe current U.S. National Policy on Breast Hyperthermia (Health Net, Inc. 2014) recommends local or regional external hyperthermia with warming up to 4 cm, only in combination with radiation therapy. From a medical point of view, this regimen is considered necessary to prevent the recurrence of breast cancer in the chest wall. Health Net, Inc. does not consider it effective or appropriate to use hyperthermia without radiation therapy, even in combination with chemotherapy or only one local/regional therapy. hyperthermia. Health Net, Inc. recommends the use of focus ultrasound (FU) hyperthermia after a preliminary course of radiation therapy, chemotherapy (CT) and hormone therapy (HT), in combination with a second course of radiation therapy (re-radiotherapy) 28-36 Gy (average 32 Gy) 3-8 courses of hyperthermia. It should be borne in mind that at T90, the maximum and average temperatures are: 39.8°C; 43.6°C and 41.2°C, respectively, and the cumulative equivalent of a minute (0.43°) of T90 is 4.58 minutes [33].

Chemistry Therapy The decision on systemic adjunctive therapies is based on the cancer phenotype defined by ER/ PR, HER2, and Ki67 score. Hormone therapy should be recommended for all patients with detected ER expression that identifies ≥1% of aggressive cancer cells. For preclimateric patients, Tamoxifen is the standard of care, and the value of ovarian suppression is not fully known. Administration of aromatase inhibitors (nonsteroidal and steroidal) and Tamoxifen to postmenopausal women is a proven treatment option for HT [7,9,11]. Indicators of chemotherapy luminal, HER2 negative These factors depend on the individual risk of breast cancer recurrence, the expected response to hormone therapy, and the patient's preferences [15,17]. Patients with luminal-B, HER2-positive cancer and treated with standard chemotherapy, HT and Trastuzumab, it should be noted that there are no data against the appointment of CT to patients in this subgroup [18,20]. Patients with non-luminal HER2-positive cancer should receive combined treatment with Pertuzumab, Trastuzumab, and Docetaxel [16,18,19,20]. Triple-negative breast cancer is recommended to be treated with adjuvant chemotherapy, with the exception of special medications. low-risk histological subtypes: medullary carcinoma or adenocystic carcinoma [14,15,17]. Chemotherapy for primary breast cancer is recommended in 4-8 cycles of anthracycline and / or taxane - based regimens. The sequential use of anthracyclines and taxanes is recommended, rather than their simultaneous use [7,9]. Trastuzumab with chemotherapy in patients with overexpression/amplification of the HER2 gene reduces the risk of cancer recurrence by approximately half and improves overall survival compared to CT alone [18,19]. With locally advanced cancer and large "operable" in some cancers, especially when mastectomy is necessary due to the size of the tumor, the use of basic systemic therapy, before surgical treatment, will allow you to achieve operability or reduce the amount of surgical intervention. All adjuvant therapies: chemotherapy, hormone therapy, and targeted therapy can also be used before surgery [16,19,20]. Bevacizumab is recommended as first-line therapy for triple-negative, metastatic breast cancer [34] only in combination with Paclitaxel, with mandatory regular monitoring of side effects: general blood test, urea/electrolytes and liver function tests; CA 15-3, blood pressure monitoring and proteinuria test.

Imuno therapy Health Net, Inc. (2014) examines the value of adoptive immunotherapy for the treatment of breast cancer and there are ongoing clinical trials to date. Health Net, Inc. believes that there are insufficient scientific studies with adequate evidence - based support for the effectiveness and benefits of adoptive immunotherapy in breast cancer treatment than treatment with interleukin-2 (IL-2) alone [37]. HealthNetInc. determined the applicability of any of the following types of adoptive immunotherapy [37,38,39,40]: 1. For the treatment of epithelial renal cell carcinoma, melanoma or other tumors, by tumor-infiltrating lymphocytes or lymphokine-activated killers activated in vitro by recombinant or natural IL-2 or other lymphokines. 2. Antigen-charged dendritic cells, for advanced breast cancer, as well as other malignancies other than prostate cancer. 3. Autologous lymphocyte therapy using peripheral T cells stimulated in vitro with OKT3

(muromonab-CD3) monoclonal antibodies conjugated with IL-2. 4. Cell therapy. All possible options for adoptive cancer immunotherapy should be considered only in clinical trials with an adequate evidence base [37]. The implementation of "gold standards" for diagnosis and treatment, careful monitoring of side effects and risk management of possible complications should guarantee the safety and effectiveness of breast cancer treatment. One of the qualitative indicators of providing services to breast cancer patients is the provision of services in the "mammology department" or in a specialized institution that provides care to a large number of breast cancer patients. The department or center should be provided with a multidisciplinary team, which should include at least: oncologist surgeon, oncologist radiotherapist, treating oncologist, radioradiologist and pathologist — all doctors should have a specialization in breast cancer. Patients should be provided with complete information about their illness and preferably written information about treatment options. Age should not be a limitation for determining the treatment strategy for breast cancer.

After organ-preserving surgery, it should be recommended to perform contralateral mammography every 1-2 years [9, 10]. Recurrent breast cancer has a poor prognosis, existing methods of treating recurrent breast cancer include: surgery (radical mastectomy or breast-preserving surgery), radiation therapy; systemic CT or HT; combination therapy (Pertuzumab, Trastuzumab and CT, Bevacizumab and CT), etc., as well as hyperthermia and adoptive immunotherapy [14,18,20]. The results of the CLEOPATRA clinical trial showed survival in patients with metastatic HER2-positive Breast cancer treated with Pertuzumab, Trastuzumab and Docetaxel, which was 18.5 months, in contrast to the control group of 12.4 months (0.51 to 0.75; P Although the level of CNS metastasis was similar in both groups, Swain et al. suggest that Pertuzumab, Trastuzumab, and Docetaxel delay the onset of CNS metastasis compared to placebo, Trastuzumab, and Docetaxel [20]. The European Medical Association (EMA) approved Bevacizumab with Paclitaxel as a first-line treatment for metastatic breast cancer, while the Food and Drug Administration (FDA) rejected it. Bevacizumab for the treatment of metastatic breast cancer due to safety concerns and a high risk of complications that exceed the expected results, until convincing results are provided. In the FDA and EMA guidelines, Bevacizumab with other chemotherapy drugs for the treatment of breast cancer is allowed only in clinical trials [7,21,23,34]. Bevacizumab (Avastin), is a recombinant human monoclonal antibody that selectively binds to and neutralizes the biological activity of human VEGF. Bevacizumab suppresses vascularization by inhibiting tumor growth It has previously shown clinical efficacy in patients with HER2-negative metastatic breast cancer. Antiangiogenic therapy with Bevacizumab leads to normalization of blood flow and subsequently to the formation of inadequate blood supply. The results of treatment are a decrease in hypoxia and interstitial pressure, as well as an increase in the delivery of chemotherapy drugs to the tumor. Bevacizumab with CT improves efficacy, including 1-year survival in patients with a poor prognosis of the disease, than in patients treated with CT alone. The total pathologic response was 18.4% in the group of patients patients receiving combined CT with Bevacizumab, in contrast to patients receiving only Erbitux, Cyclophosphamide and Docetaxel – 14.9% [14,15,34]. Bevacizumab with CT significantly increases the risk of gastrointestinal perforation, especially with taxanes or oxaplatin. Chemotherapy with Bevacizumab is associated with an increased risk of fatal adverse outcomes, especially with platinum-based chemotherapy drugs [34,35]. In addition, Bevacizumab with CT causes arterial thromboembolic complications, including stroke, coronary heart disease and myocardial infarction. risk in patients over 65 years of age [14,34,35]. Although gastrointestinal (GI) perforations can occur at any time during treatment, they most often occur within 50 days of the start of treatment. Bevacizumab is completely discontinued in patients with tracheoesophageal fistula or fistula of any nature. A common complication of Bevacizumab is hemorrhage, especially in the tumor itself [14,15,23,34,35]. The method of treating cancer with hyperthermia is currently different from the original cancer

hyperthermia, which was a hyperthermic effect on the tissue of high temperature. between 40°-45°C or 104 ° –113 ° F, without harming the surrounding healthy tissue. It is believed that heating areas of the body that contain cancer cells or heating the tumor itself can help kill cancer cells [33]. The efficacy and side effects of repeated radiation therapy plus hyperthermia (LT+HT) were evaluated in patients with post-radiation angiosarcoma of the chest and chest. Patients received an average radiation dose of 35 Gy (32-54 Gy) and 3-6 sessions of hyperthermia. Hyperthermia treatment sessions were performed several times a week after radiotherapy. Researches repeated LT+ HT, combined with or without surgery, has been shown to improve the local effect in patients with breast angiosarcoma [33]. Ali HR et al. concluded that T-cell infiltration significantly reduces the relative risk of death in all breast cancer patients, regardless of the hormonal status of ER/HER2 receptors. A total of 12,439 patients were analyzed, of which 2,674 (21%) died of breast cancer within 10 years after diagnosis. The average survival rate was 9.57 years (range 0.05-20.6 years). The analysis was carried out relatively slowly lymphocyte count, tumor morphology, and molecular subtype [39]. Geller et al. evaluated the tumor response and in vivo allogeneic expansion of natural killer cells (NK) in recurrent ovarian and breast cancers. Patients received pre-treatment with fludarabine 25 mg / m×5 doses, cyclophosphamide 60 mg / kg×2 doses, and seven patients received radical radiotherapy (RRT) 200 gy to increase the effect of immune suppression. NK cells from haplo-identical related donors were incubated in 1000 U / mL of interleukin (IL)-2 before intravenous infusion. Subcutaneous administration of IL-2 three once a week 6 doses after infusion of NK cells. Twenty patients (14 with ovarian cancer and 6 with breast cancer) were treated. The dose of NK cells was 2.16×10 cells/kg. Donor DNA was detected 7 days after administration of NK cells in 9/13 (69%) patients without RRT and in 6/7 (85%) patients after RRT. T-regulatory cells were increased by +14 per day compared to the group after pre-chemotherapy (P=0.03). The level of serum IL was increased in the group of patients after preliminary therapy (P= Patients who received RLT had a delay in restoring the blood formula (P=0.014). Geller et al. It was concluded that the adoptive transfer of haplo-identical NK cells after chemotherapeutic lymph drainage is associated with transient chimerism of the donor and may be limited by the reconstructivity of recipient T cells [37,38]. Richards, John M. et al., propose a method of lymph drainage by obtaining the original CD8+ T cells from patients after administration of cladribine; contacting the original CD8+ T cells with xenogenic, antigen-presenting cells that are loaded with one or more peptide antigens promotes the generation of activated cytotoxic T lymphocytes (CTLs) that target cells expressing the specified one or more peptide antigens. Intravenous administration of activated CTLs and two cytokines (at least) to the patient will improve the persistence of CTLs. Richards, John M. et al. believe that the method will improve the effectiveness of treatment by extending the persistence time of activated CTLs and reducing the number of infectious complications [40].Conclusions The introduction of appropriate standards for the diagnosis and treatment of breast cancer and the analysis of quality indicators for the provision of services to breast cancer patients will reduce the risk of cancer recurrence. Due to the lack of proven standards for the treatment of metastatic breast cancer, treatment of patients with metastatic/triple-negative breast cancer is recommended in well-developed, independent, prospective, randomized clinical trials. Bevacizumab, Pertuzumab, and Lapatinib are effective targeted agents, but clinical trials are needed to explore the best strategies for using targeted agents with CT. Knowledge of the molecular characteristics of cancer will make it possible to more effectively target HER2-negative metastatic breast cancer and reduce the risk of unwanted side effects and complications. New approaches to breast cancer treatment: hyperthermia, adoptive immunotherapy, new agents and chemotherapy should only be used in clinical trials until their safety and efficacy are fully confirmed.

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