

GOVERNMENT GAZETTE
OF THE HELLENIC REPUBLIC

Second Issue

Sheet No 1511

June 6, 2014

CONTENTS

DECISIONS

Provisions for the prescription and Reimbursement of Oncological Medicinal Products

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No 49516

Provisions for the prescription and Reimbursement of Oncological Medicinal Products

THE MINISTER OF HEALTH

Having considered:

1. The provisions of article 14, par. 3 of Law 3840/2010 (Gov. Gazette A 53).
2. The provisions of article 90 of the P.D. 63/2005 "Codification of legislation for the Government and the Government bodies (Gov. Gazette A 98).
3. The P.D. 119/2013 "Appointment of the Vice President of the Government, Ministers, Alternate Ministers and Deputy Ministers (Gov. A 153).
4. The Provisions of the L.D. 96/1973 and mainly article 17 as amended and in force (Gov. Gazette A 172).
5. The provisions of the P.D. 95/2000 (Gov. Gazette A 76) "Organisation of the Ministry of Health and Welfare", as amended and in force.
6. The provisions of articles 38, 39, 40 and 51 of Law 3918/2011 (Gov. Gazette A 31) as amended and in force.
7. The provisions of articles 11, 16, 17, 19, 20, 21 and 23 of Law 4052/2012 (Gov. Gazette A 41) as amended and in force.

8. The provisions of article 12 of Law 3816/2010 (Gov. Gazette A 6) as supplemented by par. 5 of article 63 of Law 3918/2011 (Gov. Gazette A 31) and the provisions of article 40 and 51 of Law 3918/2011 (A 31).
9. The provision of article 22 of Law 4213/2013.
10. Article 34 of Law 4025/2011 (Gov. Gazette 229 A).
11. The Order of the Minister of Health No 3322/4-6-2014.
12. The fact that no expenditure is incurred against the State Budget, we decide:

Article 1:

Prescription and reimbursement of Oncological Medicinal Products

1. For the prescription of specific oncological medicinal products, the existence of tests of bio-indices is defined as obligatory and a prerequisite, which justify the use of these medicinal products, in accordance with the guidelines and the international scientific data.
2. Upon publication of this decision, the indices per type of tumour are included in the table attached. Upon the suggestion of the competent scientific bodies, such as the KESY, the Hellenic Oncological Company, the Committee of the positive list of Law 3816/2010 or the Protocols Committee, by decision of the Minister of Health, the said table may be periodically renewed, as well as the conditions for the centres where the relevant tests are conducted, whose cost is obligatorily covered by EOPYY.

BIO-INDEX	TYPE OF CANCER WHOSE TREATMENT DEPENDS ON THE RESULT OF THE BIO-INDEX	PRICE (EURO)
DETECTION OF KRAS MUTATIONS (EXONS 2, 3, 4) IN HISTOLOGIC (PARAFFIN CUBE) OR CELLULAR MATERIAL	LARGE INTESTINE CANCER AND NON-MICROCELLULAR LUNG CARCINOMA	160
DETECTION OF NRAS MUTATIONS (2, 3, 4) IN HISTOLOGIC OR CELLULAR MATERIAL	LARGE INTESTINE CANCER	160
ANALYSIS OF MICRO-SATELLITE INSTABILITY OF TUMOUR DNA (MSI)	LARGE INTESTINE CANCER	120
IMMUNOCHEMICAL STUDY OF MICRO-SATELLITE INSTABILITY IN HISTOLOGIC MATERIAL (4 ANTIBODIES)	LARGE INTESTINE CANCER	80
DETECTION OF MUTATIONS OF THE EGFR GENOME (EXONS 18, 19, 20, 21) IN HISTOLOGIC MATERIAL	NON-MICROCELLULAR LUNG CARCINOMA	160
DETECTION OF PERMUTATION OF THE ALK GENOME IN HISTOLOGIC MATERIAL WITH IN SITU HYBRIDISM	NON-MICROCELLULAR LUNG CARCINOMA	120
DETECTION OF PERMUTATION OF THE ALK GENOME IN HISTOLOGIC MATERIAL WITH IMMUNOCHEMISTRY	NON-MICROCELLULAR LUNG CARCINOMA	40
DETECTION OF BRAF MUTATION V600E (EXONS 11, 15) IN HISTOLOGIC MATERIAL	MELANOMA	130 (one costs 75)
DETECTION OF OVEREXPRESSION OF MUTATIONS IN THE C-KIT/PDGFR GENOMES	STROMATIC TUMOURS OF THE GASTROINTESTINAL SYSTEM	70 PER MUTATION
IMMUNOCHEMICAL OVEREXPRESSION STUDY OF THE HER2 GENOME	CANCER OF THE BREAST AND STOMACH	40
OVEREXPRESSION STUDY OF THE HER2 GENOME WITH IN SITU HYBRIDISM (CISH, FISH)	CANCER OF THE BREAST AND STOMACH	150
IMMUNOCHEMICAL STUDY OF ESTROGENS AND	CANCER OF THE BREAST AND OVARIES	40

PROGESTIN RECEPTORS		
DETECTION OF PERMUTATION Bcr-Abl WITH RT-PCR	CHRONIC MYELOID LEUKEMIA	120
IMMUNOCHEMICAL DETECTION (6 REAGENTS) OF LYMPHOMAS	LYMPHOMAS	120 FOR ALL (20 FOR EACH ONE SEPARATELY)
DETECTION OF CHIMERIC TRANSCRIPTIONS OF BCR/ABL WITH QUALITATIVE PCR	CHRONIC AND ACUTE MYELOID LEUKEMIA, MYELOHYPERPLASTIC NEOPLASMS, ACUTE LYMPHOBLASTIC LEUKEMIA	80
DETECTION OF CHIMERIC TRANSCRIPTIONS OF BCR/ABL WITH REAL-TIME PCR	CHRONIC AND ACUTE MYELOID LEUKEMIA, MYELOHYPERPLASTIC NEOPLASMS, ACUTE LYMPHOBLASTIC LEUKEMIA	120
DETECTION OF CHIMERIC TRANSCRIPTIONS OF PML/RARA WITH QUALITATIVE PCR	ACUTE MYELOID LEUKEMIA	80
DETECTION OF CHIMERIC TRANSCRIPTIONS OF PML/RARA WITH QUALITATIVE REAL-TIME PCR	ACUTE MYELOID LEUKEMIA	120
DETECTION OF JAK2/V617F MUTATIONS WITH ALLELE SPECIFIC PCR	MYELOHYPERPLASTIC NEOPLASMS	80
MARROW KARYOTYPE/REGIONAL BLOOD OF PATIENTS WITH MALIGNANT DISEASES WITH THE USE OF MITOGENS (24, 48, 72 HOURS)	CHRONIC AND ACUTE MYELOID LEUKEMIA, MYELODYSPLASTIC SYNDROME, MYELOHYPERPLASTIC NEOPLASMS	160
MOLECULAR CYTOGENETIC STUDY (FISH) WITH THE USE OF A UNIQUE DETECTOR	ACUTE MYELOID LEUKEMIA AND MYELODYSPLASTIC SYNDROMES	150 (for each additional detector, 80)