OBJECTIVES: Reimbursement of oncological treatments by the Brazilian Public Health System (SUS) is controlled by the Authorization for High Complexity Procedures (APAC) System. Each line of treatment has an APAC code associated with a specific reimbursement value that should cover all drug expenses for one month. However, with innovation and more expensive drugs that have been launched, these fixed values may not be enough to cover drug expenses. In this context, our objective was to compare costs of recommended regimens with values reimbursed in the SUS APAC system.

METHODOLOGY: We reviewed NCCN (National Comprehensive Cancer Network) guidelines for metastatic non-small cell lung cancer (mNSCLC) and analyzed recommended chemotherapy regimens. Regimens costs were calculated and compared to the APAC value for mNSCLC, which is equivalent to only $1,302 USD ($4,439 BRL) per month. The maximum sale price for the same treatment without taxes. For the drugs that already had generics, calculations were made in two different ways: lowest price and lowest price with 30% and 50% discounts. Drug prices were retrieved from the list published by CMED (Câmara de Regulação do Mercado de Medicamentos - Regulatory Chamber of Drug Market).

RESULTS: Ten different regimens are recommended for mNSCLC, two target therapies, four chemotherapy regimens, and carboplatin + paclitaxel. Considering the lowest cost for the generic drugs, only one regimen would be covered: Carboplatin + Docetaxel. Costs ranged from of $916 to 16,500 BRL. Considering the lowest cost for the generic drugs, only one regimen would be covered: Carboplatin + Docetaxel. Costs ranged from of $916 to 16,500 BRL.

CONCLUSION: Our analysis indicated that patients might not have access to recommended treatment because the reimbursement system is not updated to the advent of new technologies.

INTRODUCTION

• Reimbursement of oncological treatments by the Brazilian Public Health System (SUS) is controlled by the Authorization for High Complexity Procedures (APAC) System.
• In this system, there is a table of procedures with a corresponding value to each oncological treatment.
• The table of procedures is based on the therapeutic indications and not on chemotherapy/ immunotherapy or hormone therapy drugs per se.
• Although chemotherapy treatment is administered in cycles, the APAC value corresponds to one month of treatment and one APAC code can be requested more than one per month.
• This means that the total cost of treatment is divided by the number of months that a patient is treated and the result of this division is the amount to be paid each month.
• Lung cancer is one of the most incident diseases in Brazil and worldwide. Non-small cell lung cancer is the most prevalent type of lung cancer and it is described as one of the most genomically diverse of all cancers.
• Several treatment options are available for advanced or metastatic mNSCLC. New technologies have been recently launched and these new findings came with an expressive increase in treatment costs.
• The aim of this study was to compare the costs of recommended treatments with the values reimbursed by the SUS APAC system.

METHODOLOGY

• We reviewed the NCCN (National Comprehensive Cancer Network) guidelines for mNSCLC and analyzed the recommended chemotherapy regimens.
• Regimens costs were calculated and compared to the APAC value for mNSCLC, which is equivalent to only $1,302 USD ($4,439 BRL) per month. (Exchange rate 1 USD = 4.439 BRL)
• This particular APAC code covers with the following description:
  • Neoplastic chemotherapy for mNSCLC with stage IIIB or IV recurrent disease, peripheral metastasis or brain metastasis (including surgery). For the drugs that already had generics, calculations were made in two different ways: lowest price and lowest price with 30% and 50% discounts.
  • Neoplastic chemotherapy with the APAC code without tax.
• All costs (MSPG) without added taxes are showed in Figure 1. For these calculations, we assumed the conservative approach of one cycle per month.

RESULTS

NCCN guidelines

• Ten different regimens are recommended for mNSCLC by NCCN guidelines: 2 first target therapies, 3 neoadjuvant-based regimens and 5 metastatic-based regimens. 3 older regimens (see Table 1).
• All drugs are used as currently available in SUS.

Table 1. Regimens Recommended for mNSCLC by NCCN guidelines

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Dose</th>
<th>CYCLES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gefitinib</td>
<td>250mg daily</td>
<td>3 cycles</td>
</tr>
<tr>
<td>Bevacizumab + Carboplatin</td>
<td>5mg/kg Amend AUC 1.0 + 250mg/m2 D1 and 08</td>
<td>3 cycles</td>
</tr>
<tr>
<td>Cisplatin + Docetaxel</td>
<td>75mg/m2 D1 and 21 (21 cycle)</td>
<td>3 cycles</td>
</tr>
</tbody>
</table>

Note: D1 = day 1; m2 = meters squared; kg = kilograms

DISCUSSION

• None of the target therapies, such as bevacizumab, erlotinib and gefitinib can be reimbursed by the APAC value for mNSCLC treatment.
• The APAC only reimburses of absolute therapies.
• This analysis shows that even if the regulatory organs responsible for Health Technology Assessment decide for the incorporation of a drug, it does not mean that patients will have access to these new findings.
• As an example, the combination of gemcitabine and cisplatin, which is more expensive than the APAC value, has been reimbursed by SUS (CMED) (the National Committee for Health Technology Incorporation) without any alteration in the APAC value.
• Advanced NSCLC has been one of the most studied types of cancer and a great variety of new drugs with significant results, are coming to the market. However, the Brazilian Public Health System still does not provide access to therapies that were launched a decade ago.
• 75% of Brazilians depend on SUS for healthcare treatment. According to the Brazilian Constitution, healthcare is a right of every citizen and the SUS system has to be provided.
• Historically, the Public System is plagued by lack of mediation, overmedication and underfunding.

• Most of the newest technologies approved by Regulatory Chambers are available for patients of the Brazilian Public Health System. That means one can have access to better treatments while others are relegated to receive older and less beneficial therapies.

CONCLUSION

• In contrast to what is expected, incorporation of technology by the government does not guarantee that the population will have access to it, particularly due to the APAC system barrier.
• The APAC system must not stop innovations in treatments, leaving patients to receive absolute therapies.
• This creates inequality between patients from the public and private system and poses against the Brazilian Constitution and the Brazilian Federal Law No. 8,069/1990, which states that all patients have equal rights to healthcare.

• Finally, the APAC system needs to be carefully reviewed in order to provide better treatments to patients and accommodate some of the innovations that are still to come.