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Title: The use of poly-L-lactic acid- SCA treatment for HIV-related oromaxillofacial lipoatrophy in Brazil: expert panel recommendations

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Abstract

Objective: To provide expert panel recommendations regarding the use of poly-L-lactic acid-SCA (PLLA-SCA) for the treatment of Human Immunodeficiency Virus – HIV - related oromaxillofacial lipoatrophy in Brazil. Methods: A multidisciplinary expert panel comprising five dermatologists and one infectious disease specialist convened an in-person meeting to discuss the contemporary patient journey, clinical practices, treatment approaches, and safety considerations related to PLLA-SCA in HIV-related facial lipoatrophy. The recommendations were based on the clinical experience of the panel members and informed by the current literature. Results: The panel considered HIV-related oromaxillofacial lipoatrophy an important psychosocial condition negatively affecting quality of life, self-image, and social interactions. PLLA-SCA was considered an effective and well-tolerated regenerative biostimulator for facial volume restoration and improvement of facial contour and skin quality in patients living with HIV. The recommendations included preferential application of PLLA-SCA to the lateral face, including temples, pre-auricular, and mandibular regions, while avoiding areas previously treated with permanent implants. The panel also emphasized individualized treatment planning, safety assessment, and multidisciplinary follow-up. Conclusion: Based on the available literature and the collective clinical experience of the panel members, PLLA-SCA may represent a safe and effective treatment option for HIV-related oromaxillofacial lipoatrophy. These expert panel recommendations provide practical clinical considerations to support individualized treatment planning and optimization of aesthetic and psychosocial outcomes in patients living with HIV.

Keywords: HIV, Quality of life, Antiretroviral Therapy, Highly Active, Patient Satisfaction.

Statement of Clinical Significance

An expert panel supports the use of poly-L-lactic acid-SCA (PLLA-SCA) as a safe and well-tolerated option for HIV-related oromaxillofacial lipoatrophy in Brazil. PLLA-SCA may assist in facial volume restoration and improvement of facial harmony, particularly in the lateral face, while avoiding areas with permanent implants.

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Introduction

The evolution of HIV infection and AIDS treatment in Brazil has seen remarkable progress since the initial case report in 1982. The advent of zidovudine (AZT) between 1988 and 1989 marked a significant milestone, effectively reducing viral load and demonstrating potent lipoatrophic effects[1,2]. Noteworthy strides were made in 1996 with the introduction of free access to antiretroviral therapy (ART), leading to improvements in patient outcomes such as the reduction in HIV transmission rates and AIDS-related mortality[1,2]. Brazil's commitment to advocating for universal HIV treatment access further solidified its global role in combating the pandemic.

The advent of Highly Active Antiretroviral Therapy (HAART) guided a new era in HIV management, although it brought important side effects, including the emergence of lipodystrophy syndromes[3]. HIV-related lipodystrophy may clinically manifest as lipoatrophy, lipohypertrophy, or mixed patterns of adipose tissue redistribution. Lipoatrophy is characterized by subcutaneous fat loss, particularly affecting the face and extremities, whereas lipohypertrophy commonly involves central or visceral fat accumulation and dorsocervical adipose tissue enlargement. These manifestations may occur simultaneously or predominate individually according to patient characteristics and antiretroviral exposure[3,4].

Among these, facial lipoatrophy has emerged as a significant concern, characterized by pronounced subcutaneous tissue loss and facial volume reduction, particularly in areas such as the malar and zygomatic regions, temples, and pre-auricular region[3]. Certain ART medications, including those containing thymidine analogs (stavudine and zidovudine), nucleoside reverse transcriptase inhibitors, and protease inhibitors, have been identified as more lipoatrophic than others[3,5]. Addressing the treatment of these morphological changes becomes pivotal not only to mitigate the well-being and quality of life impact on individuals living with HIV but also to promote treatment adherence[6.] From a pathogenic perspective, lipoatrophy has been primarily associated with mitochondrial toxicity induced by these medications, as well as potential direct effects of HIV on adipocyte function[5,6].

Historically, the reported prevalence of HIV-associated lipodystrophy in patients receiving earlier antiretroviral regimens ranged from 23% to 70%, depending on study design and duration of follow-up. Following the replacement of thymidine analogues with less lipoatrophic regimens, including tenofovir-based therapies and integrase inhibitors, the incidence of new overt lipoatrophy cases has substantially

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declined. However, established facial volume loss frequently persists in previously exposed patients, even after therapeutic switching. Furthermore, although contemporary antiretroviral therapies are associated with a marked reduction in severe forms of HIV-related lipoatrophy, these regimens are not entirely free from adipose tissue-related effects[4].

These medications belong to earlier generations of antiretroviral regimens. With the introduction of more modern therapies, the incidence of new cases of lipoatrophy has declined. However, in previously exposed patients, recovery of adipose tissue may be limited, and additional mechanisms, including chronic HIV-associated inflammation, remain under investigation. Therefore, despite advances in antiretroviral therapy, HIV-related facial lipoatrophy continues to represent an important clinical and psychosocial challenge[4].

As the landscape of HIV treatment continues to evolve, a comprehensive evaluation of facial lipoatrophy's current context and its psychosocial implications on affected patients is warranted[1,6,7]. This evaluation is particularly significant within the broader framework of various quality of life domains[7]. Considering the subjective perception of facial lipoatrophy's impact on well-being, effective treatment strategies are imperative. Injectable options such as hyaluronic acid (HA), polyacrylamide, polymethyl methacrylate (PMMA), calcium hydroxyapatite (CaHA) , and poly-l-lactic acid (PLLA-SCA) offer promising strategies for intervention[7,8].

Despite potential PMMA associated risks of granulomas and permanent results, has gained prominence in Brazil's national public health system for treating HIV-related facial lipoatrophy, following regulatory scrutiny by the National Health Surveillance Agency[10-12]. Within this landscape, PLLA-SCA emerges as a treatment modality. It is plant-derived and manufactured under stringent quality standards certified by ISO13485:2016[13]. Across all PLLA injectables (or biostimulators) currently available, Sculptra® (PLLA-SCA) was the first commercially and is the most widely studied with approval for facial aesthetic uses since 1999 in Europe; and since 2004 in the United States for the restoration and correction of the signs associated with HIV-associated lipoatrophy. In 2005, it was approved in Brazil by the National Health Surveillance Agency (ANVISA)[10] and since 2009 also for correction of nasolabial folds and other facial wrinkles. More recently, the MDR certificate encompassed the expansion of PLLA-SCA indications to include body areas such as the décolletage, gluteal region, posterior thighs, and upper arms (Haddad et al., 2025).

Previous clinical studies have demonstrated the efficacy and safety of PLLA-SCA for HIV-related facial lipoatrophy, including significant improvement in facial volume restoration, patient satisfaction, and quality of life. Progressive correction of facial lipoatrophy and sustained clinical improvement with favorable tolerability profiles over time have also been reported following PLLA-SCA treatment[14-19].

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This manuscript aims to provide expert panel recommendations offering updated insights into the patient journey in Brazil concerning the use of injectable PLLA-SCA for HIV-related oromaxillofacial lipoatrophy, including clinical perspectives and best practices for treatment.

Methods

This manuscript presents expert panel recommendations regarding the use of PLLA-SCA for HIV-related oromaxillofacial lipoatrophy, providing a clinical perspective derived from a multidisciplinary panel comprising experts in infectology and dermatology. The recommendations are based on the clinical experience of the panel members and informed by the current literature, including clinical studies, case reports, and review articles addressing the use of PLLA-SCA in the management of HIV-related facial lipoatrophy.

In September 2023, a face-to-face meeting was convened in São Paulo, Brazil, bringing together a multidisciplinary panel composed of six medical experts (AFDC, AMBV, ARTA, DF, LKMO, and LZG). Facilitated by a trained medical moderator (CK, RT), the session aimed to explore the contemporary patient journey and to provide timely clinical recommendations for the management of HIV-related facial lipoatrophy, with particular emphasis on PLLA-SCA. This collaborative effort yielded a structured sequence of recommendations, covering various aspects such as patient background, diagnosis, selection criteria, treatment options, tools and techniques, treatment sessions, severity-based variations, and safety.

The recommendations presented in this manuscript were developed based on the collective clinical experience of the panel members, supported by the available literature and routine clinical practice in the Brazilian healthcare setting.

Results

Patient background

HIV-related lipodystrophy may clinically manifest as lipohypertrophy, lipoatrophy, or mixed patterns of adipose tissue redistribution. Facial lipoatrophy represents one of the most stigmatizing manifestations, particularly among patients previously exposed to older-generation antiretroviral regimens, including thymidine analogues such as stavudine and zidovudine[3-6]. Although the incidence of new lipoatrophy cases has declined following the introduction of more contemporary antiretroviral therapies, established facial volume loss frequently persists in previously exposed patients, even after therapeutic switching[4,20]. In this context, HIV-related oromaxillofacial lipoatrophy continues to represent an important functional, aesthetic, and psychosocial concern.

Patients with HIV-related oromaxillofacial lipoatrophy frequently report discomfort and stigmatization, negatively impacting quality of life, self-image, and social interactions. Common treatment

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goals include volumetric replacement, facial contour restoration, and improvement of associated skin laxity. According to the panel experience and available literature, HIV-associated chronic inflammation and mitochondrial toxicity may contribute to accelerated cellular senescence, particularly in patients already presenting significant facial aging. Therefore, both the clinical presentation and patient expectations frequently involve volumetric and aging-related concerns.

Diagnosis

The diagnosis of HIV-related oromaxillofacial lipoatrophy is predominantly clinical, and there is currently no globally adopted standard classification system. Infectologists frequently represent the first point of contact for these patients and may subsequently refer them to dermatologists. Referral and treatment decisions are generally based on the patient's clinical condition, comorbidities, viral load control, and CD4 levels.

Clinical assessment remains the cornerstone of diagnosis, with severity commonly categorized as mild, moderate, or severe according to the degree of facial volume loss and aesthetic impact. Clinical findings commonly include loss of malar and temporal volume, zygomatic prominence, pre-auricular depression, mandibular contour changes, and increased visibility of facial bony landmarks secondary to subcutaneous fat loss[3,5,21]. In Brazil, the Facial Lipoatrophy Index proposed by Serra et al.[21] is commonly used as a reference tool for clinical evaluation. The index assesses the severity of facial lipoatrophy based on anatomical involvement and the extent of soft tissue loss, particularly in the zygomatic region, contributing to standardized clinical assessment and therapeutic planning (Table 1).

Table 1. Oromaxillofacial lipoatrophy index for severity assessment of the affected zygomatic region in HIV-infected patients.

Score	0	1	2	3	4	5
Depth (D)	None	Mild	Moderate	Severe	Very severe	-
Area (A)	0	< 20%	21 < 50%	51 < 70%	71 < 90%	91 < 100

*Adapted from: Serra et al., 2013.

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Patient selection criteria

According to the panel recommendations, patients presenting HIV-related oromaxillofacial lipoatrophy may be considered eligible for PLLA-SCA treatment following appropriate clinical evaluation. Treatment indication should be individualized according to the patient's clinical condition, degree of facial volume loss, aesthetic concerns, and overall treatment goals. Young patients who acquired HIV through vertical transmission, as well as patients presenting associated skin laxity and signs of facial senescence, may particularly benefit from treatment. In these patients, PLLA-SCA may contribute not only to volumetric restoration but also to gradual improvement in facial contour and skin quality. However, the panel recommends avoiding PLLA-SCA application in anatomical areas previously treated with permanent implants such as PMMA.

Treatment options

The current treatment options for HIV-related oromaxillofacial lipoatrophy include autologous fat PMMA, HA, PLLA-SCA and CaHA. According to the panel recommendations, these approaches may be used individually or in combination, depending on individual patient characteristics and treatment goals. PLLA-SCA is preferentially recommended for the lateral face, including temples, pre-auricular, and mandibular regions, whereas HA (NASHA® or OBT ™) or PMMA may be considered for the middle third of the face **(Figure 1)**. The panel emphasizes that PLLA-SCA should be avoided in areas with pre-existing permanent implants, such as PMMA. The choice of treatment depends on individual patient characteristics and preferences, and according to the experts' experience, the maximum number of 8 PLLA-SCA vials in total should be regarded[22].

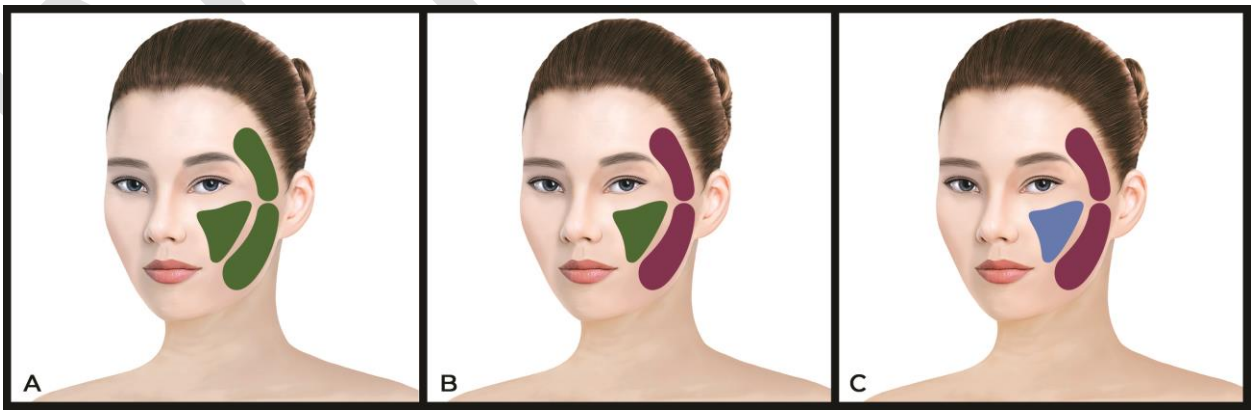


Figure 1. (A) Areas in green that can be treated individually with PMMA; (B) PLLA-SCA is indicated to be applied to the lateral face (areas in magenta), including temples, pre-auricular and mandibular line, with PMMA in the middle third of the face or (C) with HA filler in blue (NASHA® or OBT™) in the middle third of the face.

Tools and techniques

The panel recommends the use of 22-gauge to 25-gauge cannulas for PLLA-SCA treatment, in accordance with conventional injection techniques commonly adopted in clinical practice. According to the panel experience, PLLA-SCA is preferentially applied using retroinjection and fanning techniques in the subcutaneous plane, particularly in the lateral facial regions, including the temples, pre-auricular area, and mandibular line. Treatment planning should consider the degree of facial volume loss, skin quality, and individual anatomical characteristics.

The panel emphasizes the importance of careful product distribution, low-pressure injection, and avoidance of overcorrection to minimize the risk of papules, nodules, and contour irregularities. Anatomical areas previously treated with permanent fillers should be approached with caution, particularly in patients with prior PMMA injections. Immediate post-procedure massage and appropriate follow-up are also recommended as part of routine clinical management.

Treatment sessions

Personalizing treatment plans should align with each patient's specific needs and goals. The panel generally recommends the use of one to two PLLA-SCA vials per session, although selected cases may require three vials during a single treatment session. According to the panel recommendations, treatment sessions should generally be performed with intervals of at least four weeks, depending on clinical response and individual treatment planning. The standard dilution time should follow the product instruction for use information. Regarding dilution volume, the panelists noted the use of 8 mL of sterile water for injection, with the option of adding 1 mL of lidocaine to achieve a final injection volume (9 mL) is mentioned by the panelists. Post-procedure follow-up is recommended to evaluate clinical response, monitor potential adverse events, and determine the need for additional treatment sessions.

Severity-based variations

The number of treatment sessions may vary based on the severity of lipoatrophy at diagnosis, with greater severity potentially necessitating a higher number of sessions and the combination of PLLA-SCA with other treatment modalities, such as PMMA, and HA to provide an immediate result in distinct anatomic areas.

Safety considerations

Patients with any uncontrolled clinical condition or recent opportunistic infection within the past six months that may increase procedural risk should be carefully evaluated. Concurrent use of

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anticoagulants, immunomodulators, immunosuppressants, or chemotherapy warrants individualized assessment because of potential interactions and complications. According to the panel recommendations, detectable viral load or active rheumatologic disease should be carefully evaluated before treatment.

The panel recommends that clinical indication for PLLA-SCA treatment should consider the patient's overall clinical and immunological status, including recent evaluation of CD4+ cell count and viral load, in accordance with current medical assessment and institutional protocols. According to the panel experience, patients presenting stable clinical condition and controlled viral load (<200 copies/mL) may be considered eligible for treatment following appropriate medical evaluation, including selected cases with immunological failure.

The presence of bacterial or viral infections involving the face, oral cavity, or upper respiratory tract requires additional caution before treatment. Pregnancy is considered a contraindication for the procedure.

Injection-related adverse events, including pain, tenderness, bruising, edema, or swelling, may occur after treatment and usually resolve spontaneously. Early adverse events commonly include edema, tenderness, bruising, pain, and mild inflammatory signs occurring within the first days after treatment, whereas delayed adverse events may include papules or nodules developing weeks to months after injection. According to the available literature and panel experience, appropriate injection technique, careful product distribution, massage, and clinical follow-up may contribute to minimizing these complications. Persistent inflammatory signs, progressive swelling, or delayed nodules should prompt additional clinical evaluation to exclude infectious or granulomatous reactions.

The recommendations derived from these discussions form the basis of the practical recommendations presented in this manuscript **(Table 2)**, reflecting the panel's clinical experience in the management of HIV-related oromaxillofacial lipoatrophy.

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Table 2. Clinical recommendations on diagnosis and treatment of HIV-related oromaxillofacial lipoatrophy.

	Clinical recommendations
Patient Background	• Discomfort and stigmatization with reduced quality of life and social interactions. • Volumetric replacement and correction of skin laxity. • Addressing volumetric and age-related concerns. • Persistent facial volume loss may occur even after antiretroviral therapeutic switching in previously exposed patients.
Diagnosis	• Diagnosis is predominantly clinical, lacking a globally adopted standard classification. • Facial lipoatrophy index - severity categorized as mild, moderate, or severe.
Patient Selection Criteria	• Eligibility for PLLA-SCA treatment included all patients experiencing facial lipoatrophy due to HIV. • No universally established minimum or maximum age criteria. • Young patients infected by vertical transmission, and associated skin laxity and signs of senescence. • PLLA-SCA is not indicated in anatomical areas that have already received permanent implants, such as PMMA.
Treatment Options	• PMMA, Hyaluronic Acid (HA), and PLLA-SCA - individually or combined in the same session. • PLLA-SCA preferentially recommended for the lateral face, including temples, pre-auricular, and mandibular regions. • HA (NASHA® or OBT™ technologies) or PMMA may be considered for the middle third of the face. • Combination treatment approaches may be considered according to patient characteristics and treatment goals. • Up to eight PLLA-SCA vials in total may be considered according to clinical severity and treatment planning.
Tools and Techniques	• Recommended a cannula with a gauge size between 22G and 25G. • Retroinjection and fanning techniques in the subcutaneous plane. • Careful product distribution, low-pressure injection, and avoidance of overcorrection.

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	• Immediate post-procedure massage recommended.
Treatment Sessions	• Customization of the treatment. • 1 to 2 vials per treatment session, with immediate dilution or within 72 hours. • 8ml of sterile water for injection. • 1 ml of lidocaine immediately before application. • Treatment sessions generally performed with intervals of at least four weeks. • Post-procedure follow-up recommended to evaluate clinical response and adverse events.
Severity-Based Variations	• Number of treatment sessions may vary based on the severity of lipoatrophy at diagnosis. • Greater severity potentially necessitating a higher number of sessions and the combination of PLLA-SCA with other treatment modalities, such as PMMA, and HA.
Safety Directive	• Patient evaluation: current medical status. • Infection control • Viral load and CD4+ status should be considered according to clinical evaluation and institutional protocols. • Adherence to standards: minimize potential adverse events.

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Discussion

HIV-related oromaxillofacial lipoatrophy remains an important clinical and psychosocial condition despite advances in antiretroviral therapy. Although the incidence of new lipoatrophy cases has declined following the introduction of contemporary antiretroviral regimens, particularly those based on tenofovir and integrase inhibitors, established facial volume loss frequently persists in previously exposed patients, even after therapeutic switching[4]. In this context, the present manuscript reflects the collaboration of a multidisciplinary panel comprising five dermatologists and one infectologist with extensive clinical and academic experience in the management of HIV-related oromaxillofacial lipoatrophy within the Brazilian healthcare setting. The discussions focused on the patient journey, clinical applications of PLLA-SCA, safety considerations, and the role of combined treatment approaches for facial rehabilitation.

The psychosocial burden associated with HIV-related facial lipoatrophy has been consistently described in the literature[8,9]. Facial volume loss may negatively affect self-image, quality of life, and social

interactions, in addition to contributing to HIV-related stigmatization[3,8,9]. In many patients, treatment goals extend beyond volumetric correction alone and also include improvement of facial contour and associated skin laxity. Chronic HIV infection, mitochondrial toxicity, and long-term antiretroviral exposure may contribute to accelerated facial aging and skin quality changes[20,23]. In this setting, PLLA-SCA may contribute not only to volumetric restoration but also to gradual improvement in skin quality and facial contour through collagen biostimulation[24,25].

The current literature supports the use of PLLA-SCA as an effective and well-tolerated treatment option for HIV-related facial lipoatrophy[14-19,25,26]. Jagdeo et al.[25] highlighted the potential role of filler agents in improving quality of life and psychological well-being in patients living with HIV, while also emphasizing the importance of individualized treatment planning and careful product selection. Hyaluronic acid fillers may provide immediate correction in selected anatomical regions, whereas PLLA-SCA may be particularly useful in broader areas of facial volume loss and skin quality gradual improvement. Therefore, combined treatment approaches may represent an important strategy in selected patients according to clinical presentation and treatment goals.

The VEGA trial by Valantin et al.[14] demonstrated the efficacy of PLLA-SCA implants in the correction of HIV-related facial lipoatrophy. Additional studies by Moyle et al.[15,16] and Bassichis et al.[17] further supported the long-term safety and efficacy of PLLA-SCA in this clinical setting. More recent investigations have also reinforced the role of optimized dilution protocols and individualized treatment planning in improving treatment tolerability and clinical outcomes[13].

The recommendations proposed by the panel emphasize individualized treatment planning, careful patient selection, and attention to safety considerations. Clinical evaluation remains the cornerstone of diagnosis, particularly considering the absence of a universally adopted classification system for HIV-related oromaxillofacial lipoatrophy[21]. In the Brazilian healthcare setting, multidisciplinary management involving infectologists, dermatologists, dentists, and oral medicine specialists may contribute to optimized diagnosis, treatment planning, and longitudinal patient care.

This manuscript has limitations inherent to expert panel-based recommendations, including the limited number of specialists involved, the potential influence of individual clinical experience, and the absence of primary patient-level data or formal consensus methodology. In addition, some recommendations reflect clinical expertise within the Brazilian healthcare setting, where high-quality comparative evidence regarding treatment strategies for HIV-related facial lipoatrophy remains limited.

In conclusion, based on the available literature and the collective clinical experience of the panel members, PLLA-SCA may be considered an effective and well-tolerated treatment option for patients with HIV-related oromaxillofacial lipoatrophy. The treatment may contribute to facial volume restoration, improvement in facial contour and skin quality, and reduction of the psychosocial burden associated with

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facial lipoatrophy. Careful clinical evaluation, individualized treatment planning, and multidisciplinary follow-up remain essential for optimized clinical outcomes.

Author's Contributions:

LKMO: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

ARTA: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

AMBV: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

AFC: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

DF: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

LZG: Approval of the final version of the manuscript; intellectual and active participation in the expert panel; critical review of the manuscript.

RT: Approval of the final version of the manuscript; study design and planning; effective participation in research guidance; critical review of the literature; critical review of the manuscript.

CK: Approval of the final version of the manuscript; study design and planning; effective participation in research guidance; critical review of the literature; critical review of the manuscript.

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Conflict of interest statement: Drs. **LKMO**, **ARTA**, **AMBV**, **AFC**, **DF** and **LZG** have worked as advisors for Galderma Brazil. Drs. **RT** and **CK** are Medical Managers for Galderma Brazil.

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