Real-world use of MART in moderate–severe asthma: results from the Italian WAMP survey among healthcare professionals and patients

Running header: **Real-world use of MART in moderate–severe asthma**

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Survey WAMP – HCPs

SCREENING	
A1. What is your **Specialty**?	1. General Medicine 2. Pneumology 3. Allergology 4. More *Thank you and close*
A2. How many years have you been practicing your profession?	|__|__|__|__| *Accepted range 3–35 years seniority, otherwise thank and close*
A3. In which region do you carry out your activity?	_____ *Check the quotas by region*
A4. Do you personally **see and treat patients with asthma**?	1. Yes 2. No *Thank you and close*
A5. Are you **directly responsible for the therapeutic choices** to be made on patients with asthma that you see as part of your clinical activity?	1. Yes 2. No *Thank you and close*
A6. How many patients diagnosed with asthma have come to your office for any reason <u>in the last 90 days?</u> In the count, consider the same patient visited more than once as the only person in the count.	|__|__|__|__| *IF Pneumology or Allergology at A1 minimum value 30 otherwise thank and close* *IF General Medicine at A1 minimum value 15 otherwise thank and close*

We ask you to refer to this severity rating for the assessment

SEVERITY LEVEL	CLINICAL FEATURES
MILD ASTHMA	Patient treated using ICS/formoterol as needed or low-dose ICS with SABA as needed
MODERATE ASTHMA	Patient treated with low- or medium-dose ICS/LABA
SEVERE ASTHMA	Patient not controlled despite adherence to optimized maximal inhalation therapy or who worsens when maximal treatment intensity is reduced

(The classification of asthma severity according to the 2023 GINA guidelines)

A7. And of ___ (number indicated at A6) patients with asthma <u>seen in the last 90 days</u>, **how many are treated exclusively as needed (mild asthma) and how many instead follow continuous therapy (moderate-severe asthma)?** CONTROL: value ≤A6	a. |__|__|__|– treated only as needed (mild asthma) b. |__|__|__|– **treated continuously and possibly as needed (moderate–severe asthma)**

Dear Doctor,
Below is the glossary with the acronyms, and related details, which you will find included in the questionnaire to make the response from all clinicians homogeneous.
GINA = Global Initiative for Asthma
ICS = Inhaled Corticosteroids (inhaled corticosteroids)
LABA = Long-Acting Beta Agonist (long-acting β2-agonists)
LAMA = Long-Acting Muscarinic Antagonists
MART = Maintenance and Reliever Therapy
SABA = Short-Acting Beta Agonist (short-acting β2-agonists)
SMART = Single-Inhaler Maintenance and Reliever Therapy

GINA INTERNATIONAL REPORT AND USE OF THERAPEUTIC PATHWAYS

The current version of the international GINA document identifies two different pathways for pharmacological treatment in adults and adolescents

- Track 1: ICS/Formoterol as needed in steps 1 and 2, then as maintenance and as needed (MART/SMART strategy) in steps 3, 4 and 5, which are characterized by increasing maintenance doses of ICS.
- Track 2: an ICS each time you take a SABA or maintenance ICS (+SABA as needed) in steps 1 and 2, respectively, then ICS/LABA at increasing doses of ICS + SABA as needed, in steps 3, 4 and 5

As another control therapy option for both pathways, the addition of the LAMA in step 4 and as the first choice in step 5 of both pathways is reported.

A8. Could you tell me if in the current version of the international GINA document one Track is indicated as preferential rather than the other?	1. Yes, route 1 is indicated as preferential 2. Yes, route 2 is indicated as preferential 3. No route is indicated as preferential 4. I am not yet aware of it
IF Pulmonologist or Allergist at A1 A9. Have you done 100% of the moderate–severe asthmatic patients you treat, out of-how many use Track 1 and how many use Track 2? *SE GP to A1* A9_b Have you done 100% of the moderate–severe asthmatic patients you follow, how many are used in Track 1 and how many in Track 2?	at. |__|__|__|% – uses/is used Track 1 b. |__|__|__|% – uses/is used Track 2 Total 100%
A9_1. What are the reasons for using Track 1? A9_2. And what are the reasons for using Track 2?	Indicated by the guidelines Greater anti-inflammatory action Increased compliance Greater effectiveness in symptoms Greater efficacy on airway compromise Greater efficacy on exacerbations Patients with mild symptoms Patients with severe symptoms Greater convenience for the patient/ single device (T1) Use of the drug-product in single administration (T2) Failure of Track 1 (T2) Failure of Track 2 (T1) ICS/LABA preference over SABA (T1) Other (specify) _____

MART THERAPY

A10. I would like to ask you to indicate which of the following statements you think is **the most correct for defining MART therapy**	1. Administer the drug both as background therapy and as needed when symptoms occur 2. Administer medication as needed only when symptoms occur 3. Administer the drug as background therapy and add salbutamol when symptoms occur 4. Other (specify) _____
A11. Have you made 100% of the moderate-severe asthmatic patients you follow, **how many do you use/are used MART therapy and how many other therapeutic approaches?**	at. |__|__|__|% – uses/is used MART therapy (maintenance and need therapy) b. |__|__|__|% – uses/other therapeutic approaches are used Total 100%
ICS/LABA/SABA	
A12. In your moderate–severe asthmatic patients, when ICS/formoterol inhalation therapy is prescribed according to the MART scheme, are you also prescribed SABA?	1. Yes ☐ 2. No ☐

A13. In what % the following therapeutic approaches are used to treat a moderate–severe asthmatic patient with the combination of...

ICS-formoterol therapy	**ICS-LABA (other than formoterol) therapy**
at. |__|__|__|% – administration as needed	at. |__|__|__|% – administration as needed
b. |__|__|__|% – maintenance and on-demand administration using a single inhaler	b. |__|__|__|% – maintenance and on-demand administration using a single inhaler
c. |__|__|__|% – maintenance administration with one inhaler and SABA as needed with a different inhaler	c. |__|__|__|% – maintenance administration with one inhaler and SABA as needed with a different inhaler

PHARMACOLOGICAL TREATMENTS OF ASTHMATIC PATIENTS	
A14. Now let's address **the case of the patient with moderate-to-severe asthma treated with medium-dose ICS/LABA who continues to experience symptoms**. Which of the following therapies would you propose to control the symptoms?	1. Increase the dosage of ICS 2. Add the BLADE (triple open in multiple inhalers) 3. Switch to medium dose ICS-LABA-LAMA (triple therapy in a single inhaler) 4. Switch to high-dose ICS-LABA-LAMA (triple therapy in a single inhaler) 5. Directly add a biologic drug 6. Add oral corticosteroid 7. Other (please specify): _____
A15. And when faced with a **patient with moderate-to-severe asthma treated with medium-dose ICS/LABA who experiences a flare-up**, which of the therapies proposed here would you propose to reduce the number of further flare-ups?	1. Increase the dosage of ICS 2. Add the BLADE (triple open in multiple inhalers) 3. Switch to medium dose ICS-LABA-LAMA (triple therapy in a single inhaler) 4. Switch to high-dose ICS-LABA-LAMA (triple therapy in a single inhaler) 5. Directly add a biologic drug 6. Add oral corticosteroid 7. Other (specify): _____

TREATMENT MANAGEMENT		
A16. In the management of the treatment of moderate-to-severe asthmatic patients, **what do you consider to be the strengths (main advantages) of the use of**:	**SABA** a. Rapid onset of action b. Duration of action c. No steroid d. Ease of prescription e. Dosing flexibility f. Accessibility and usability for the patient g. Other (specify) _____	**ICS-formoterol** a. Rapid onset of action b. Duration of action c. Presence of steroid d. Ease of prescription e. Dosing flexibility f. Accessibility and usability for the patient g. Other (specify___) ___
A17. How useful do you think **it is to administer inhalation therapy once a day and how much do you administer it several times a day**?	a. Administration: 1 x daily 1. A lot 2. Enough 3. Neither useful nor not useful 4. Little 5. Not at all b. Administration several times a day 1. A lot 2. Enough 3. Neither useful nor not useful 4. Little 5. Not at all	

FLARE	
A18. Could you **order**, according to a succession of decreasing importance, the following **objectives in the process of choosing a therapy in patients with moderate–severe asthma**?	1. Reduction in the number of exacerbations 2. Reduction of symptoms 3. Corticosteroid sparing 4. Functional improvement (spirometry)
Definition: Severe asthma exacerbation is defined as a situation that requires use of systemic corticosteroids for at least 3 days. Moderate is defined as a situation that, for example, requires a change of therapy consisting of an increase from the standard use of SABA for 2 consecutive days (minimum increase: 4 puffs per day), or, 1 visit to an emergency room or doctor's office, for the treatment of asthma that does not require systemic corticosteroids.	
A19. Done 100% of your moderate-to-severe asthmatic patients **how many have had at least one moderate-to-severe asthmatic exacerbation in the last 12 months?**	|__|__|__|%
A20. The importance of using a single inhaler compared to several inhalers is considered an improvement in various aspects. **In your opinion, which of** the **following are the three most important aspects that can be positively influenced by the use of a single inhaler**?	a. Adhesion b. Use of health resources c. Cost-effectiveness d. Respiratory function e. Quality of life f. Risk of errors g. Practicality

WAMP Patient Questionnaire

Profile/Medical History	
A21. What is your **year of birth**?	|__|__|__|__|
A22. Could you indicate your **gender**?	1. Masculine 2. Female 3. Does not indicate
A23. In which **region do you live**?	(drop-down menu with regions)
A24. What is your level of **education**?	1. Elementary school leaving certificate 2. Middle school diploma 3. Diploma 4. Degree 5. Does not indicate
A25. What type of **area** do you live in?	1. Big City - Center 2. Big City - Suburbs 3. City 4. Country 5. Rural area 6. Does not indicate
6. How **old** were you **diagnosed with** asthma?	|__|__|
7. **Do you smoke** cigarettes, cigars, pipes and/or e-cigarettes daily?	1. Yes 2. No
8. Do any of the people who live with you **smoke** cigarettes, cigars, pipes and/or e-cigarettes on a daily basis?	1. Yes 2. No

9. What **medications have you taken daily as maintenance therapy for asthma** over the past month? (multiple choice)	a. Abrif b. Aircort c. Airflusal Forspiro d. Airflusal Sprayhaler e. Airsus f. Airsusgen g. Aliflus h. Aliflus Diskus i. Alvesco j. Asmanex k. Together l. Atectura Breezhaler m. Atimos n. Beclomethasone and Formoterol DOC o. Beclomethasone and Formoterol MYLAN p. Becotide q. Biskus r. Breva s. Bronchovaleas t. Budesonide Viatris u. Clenil v. Clenil Compositum w. Clenilexx x. Clenilexx with Autohaler y. Duoresp Spiromax z. Enerzair Breezhaler aa. Flixotide bb. Flixotide Diskus cc. Fluspiral dd. Fluspiral Diskus ee. Fluticasone DOC ff. Flutiform gg. Fobuler easyhaler hh. Foradil ii. Formodual jj. Formodual NEXThaler kk. Foster ll. Foster NEXThaler mm. Gibiter easyhaler nn. Hirobriz Breezhaler oo. Inuver pp. Inuver NEXThaler qq. Miflonide Breezhaler rr. Onbrez Breezhaler ss. Oxis Turbohaler tt. Pulmelia uu. Relvar Ellipta vv. Revinty Ellipta ww. Rolenium xx. Safubref yy. Safumix zz. Salbutamol Sandoz aaa. Salmeterol and Fluticasone bbb. Seretide ccc. Seretide Diskus ddd. Serevent eee. Serevent Diskus fff. Sinestic

	ggg. Striverdi Respimat hhh. Symbicort Turbohaler iii. Trimbow jjj. Ventolin **if you do not indicate at least one of the moderate/severe asthma products (ICS-LABA or Tripla) → close**
For each drug indicated in Dom. 9. Ask "Frequency of use" (Sun. 10.), "Device" (Sun. 11.), "Dosage" (Sun. 12.) and "Cadenza" (Dom. 13.)	
10. How **often** do you take [*insert medication name*]?	1. Regularly, several times a day 2. Regularly, 1 time a day 3. Only when I have symptoms 4. Other (specify) _____
10th. This frequency of intake **reflects the exact indications of the doctor who prescribed the product or is the result of his personal experience** in the management of his condition?	1. This is what the doctor prescribes 2. It is the result of my experience
11. What **device** do you take [*insert medication name*] with?	1. With spray inhaler 2. With powder inhaler 3. Other (specify) _____
11a. The **Correct use of the inhaler**?	1. Yes, in great detail 2. Yes, broadly speaking 3. No
12. What **dosage** do you take [*insert drug name*]? (indicate the dosage indicated on the product packaging)	_____
13. How **often** does [insert drug name] take?	1. Daily on a regular basis (→13th only) 2. Only in case of symptoms (→13b only) 3. Both on a regular basis and in the event of symptoms (→13a/13b)
13th It could specify **The scheme used** for recruitment **Daily** On a regular basis?	___ puff ___ times a day
13b. Could you specify the **Scheme used** for recruitment in **if symptoms appear**?	___ puff ___ times a day
14. Do you have **any other pathologies** besides asthma? (multiple choice)	a. No, **single answer** b. Rhinitis c. Sinusitis d. Nasal polyposis e. Obstructive sleep apnea (OSAS) f. Cardiovascular diseases g. Hypertension

	h. Renal i. Gastroesophageal reflux j. Obesity k. Diabetes l. Depression/anxiety m. Other (specify) _____
15. What are the symptoms of asthma that you experience most frequently? (multiple choice)	a. Cough b. Wheezing c. Chest tightness d. Nocturnal awakenings e. Breathlessness (dyspnoea) on exertion f. Breathlessness (dyspnoea) at rest g. Other (specify) _____
For each symptom indicated in Dom. 15 ask for the "frequency" (Dom. 16.)	
16. How **often** has this symptomatology occurred in the **last 4 weeks**?	1. Never 2. Once or twice a week 3. 3–6 times a week 4. Daily 5. More than once a day
17. How would you describe the **current level of severity** of your asthma?	1. Light 2. Moderate 3. Severe
18. Why **do you think this is the current level of severity** of your asthma?	1. Indication provided by the doctor who follows me 2. Explicit test result 3. For the type of treatment I am following 4. Other (specify) _____

Asthma Management/Medication	
19. Which **medical figure is currently followed** for the management/treatment of asthma?	1. The general practitioner 2. A pulmonologist 3. An allergist 4. An otolaryngologist Another doctor (specify) _____
20. Do you have regular **asthma check-ups**?	1. Yes 2. No
21. How would you define your **asthma control** over the **past 4 weeks**?	1. Very good 2. Good 3. Sufficient 4. Scarce 5. Insufficient
22. Thinking about your current asthma management, which of the following best **describes your doctor's prescribed treatment regimen**?	1. I use only one inhaler for daily checking/maintenance 2. I use only one rescue inhaler as needed only if necessary to relieve symptoms 3. I use one inhaler for daily checking/maintenance and another rescue inhaler as needed in case of need 4. I use the same inhaler for both daily use and as an inhaler as needed in case of need

23. *Some inhalers can be used both as a daily asthma control/maintenance tool, and as a device to be used in case of need/crisis.* **Are you aware of the existence of this type of asthma management device?**	1. Yes (→23.a) 2. No (→D25.)
23.a **Has a doctor ever prescribed a** therapy **of this type**?	1. Yes 2. No (→D25.)
24. When you were prescribed this therapy for the treatment of asthma, were you also prescribed **another inhaler to use in case of need/crisis**?	1. Yes, → which one? _____ 2. No
25. What are the **characteristics of an inhaler** that you consider particularly important? (multiple choice)	a. Speed of action b. Spray formulation c. Powder formulation d. Presence of a counter of the doses delivered e. Indicator of the dose actually delivered f. Small size/Easy handling g. Other (specify) _____

Access to care	
26. What are the **limitations** you encounter **in accessing asthma treatment**? (multiple choice)	a. No → single answer b. Difficulty in making an appointment for a specialist check-up c. Prescription of the Therapeutic Plan by the Specialist d. Difficulty receiving phone or email consultations e. Follow-up intervals that are too long f. Little time dedicated to the visit g. Difficulty understanding my problems/needs h. Other (specify) _____
27. What **information material for the correct management of therapy** would you consider useful to receive when prescribing a product for the treatment of asthma? (multiple choice)	a. No → single answer b. Information leaflets on the disease in general c. Information leaflets with a detailed description of the medication and the correct use of the inhaler d. Information leaflets for family members with tips for daily support and first aid techniques in case of emergency e. Smartphone apps that help monitor symptoms, remind them to take medication and provide personalized suggestions f. Other (specify) _____
28. Are you **satisfied with the information** you received from your doctor about your state of health?	1. Yes, completely 2. Yes, although I would like to have further clarification 3. No