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Efficacy of Paxlovid and Lagevrio for COVID-19 Infection in Patients With Inflammatory Bowel Disease: A Propensity-Matched Study

The world has been faced with the coronavirus disease 2019 (COVID-19) pandemic. Several antiviral medications have been granted emergency use authorization for treatment of patients with COVID-19 including Paxlovid (nirmatrelvir and ritonavir) (Pfizer. Location, New York City, NY) and Lagevrio (molnupiravir) (Merck, Kenilworth, NJ).¹ There are no data on the use of these medications in patients with inflammatory bowel disease (IBD) who develop a COVID-19 infection. This report compares the outcomes of patients with IBD who received antiviral medications for COVID-19 with those who did not and with non-IBD patients who received antiviral medications.

A retrospective cohort study was performed using TriNetX (Cambridge, MA) which provides real-time access to deidentified electronic health records of more than 78 million patients. A real-time search and analysis of the TriNetX platform was conducted through August 18, 2022. Patients with IBD were identified using the International Classification of Diseases, 9th and 10th revisions, Clinical Modification codes plus RxNorm codes for any IBD-related medication (Supplementary Tables 1 and 2). We identified patients who received Paxlovid or Lagevrio (Table 1). The IBD control cohort included patients with IBD and COVID-19 who did not receive Paxlovid or Lagevrio. The non-IBD control cohort included patients without IBD or other immune-mediated inflammatory diseases who received Paxlovid or Lagevrio. The primary outcome was to assess the risk of any-cause hospitalization within 48 hours and 30 days after initiation of COVID-19 antiviral therapies or diagnosis of COVID-19. Secondary outcomes included the risk for intensive care unit (ICU) care, intubation/respiratory support, and mortality. All statistical analyses were conducted using the TriNetX software. Propensity-score matching and statistical analyses are described in Supplementary Table 1.

Of 29,598 patients with IBD and COVID-19, 532 (1.7%) received Paxlovid (mean age, 55.2 ± 16.2 y; female, 62%). A total of 78% received Paxlovid after developing COVID-19 for the first time, of whom 97% received Paxlovid within 24 hours of diagnosis. Of these patients, 94 (17.6%) had received at least 2 doses of the COVID-19 vaccine. Seventy-nine (84%) patients received the BNT162b2 (Pfizer, New York City, NY) vaccine and 15 (16%) received the messenger RNA-1273 (Moderna, Merck, Kenilworth, NJ) vaccine. Only 27 (5%) patients had received a COVID-19 vaccine within 6 months before Paxlovid prescription. Supplementary Table 1 shows the comparison between demographics, comorbid diseases, IBD types, and medications between the Paxlovid and control cohorts. The overall rate of hospitalization was as high as 1.8% in patients with IBD who received Paxlovid compared with 5% in the IBD control cohort. After propensity-score matching, the Paxlovid cohort had a decreased risk of hospitalization (adjusted odds ratio [aOR], 0.35; 95% CI, 0.17–0.74) compared with the IBD control cohort. No patients died, required ICU care, or intubation/respiratory support in the Paxlovid arm while as many as 1.8% of patients in the IBD control arm died (Table 1). After propensity-score matching, there was no difference in risk of hospitalization (aOR, 1; 95% CI, 0.41–2.43) between the Paxlovid and non-IBD control cohort that also received Paxlovid. No patients died, required ICU care, or intubation/respiratory support in these 2 cohorts.

A total of 150 patients with IBD (mean age, 59.6 ± 16.5 y; female, 67%) received Lagevrio. Sixty-four percent received Lagevrio after developing COVID-19 for the first time, and 85% of these patients received Lagevrio within 24 hours of diagnosis. Of these patients, 13 (8.6%) received at least 2 doses of COVID-19 vaccine. Supplementary Table 2 shows the comparison between demographics, comorbid diseases, IBD types, and medications between the Lagevrio and control cohorts. The overall rate of hospitalization was 6.7% in patients with IBD who received Lagevrio compared with 8.7% in the IBD control cohort (Table 1). After propensity-score matching, there was no difference in risk of hospitalization (aOR, 0.75; 95% CI, 0.31–1.77) between the Lagevrio and IBD control cohort. After propensity-score matching, there was no difference in risk of hospitalization (aOR, 1; 95% CI, 0.40–2.31) between the molnupiravir and non-IBD control cohort. No patients in the molnupiravir cohort died, required ICU care, or intubation/respiratory support.

Abbreviations used in this paper: aOR, adjusted odds ratio; COVID-19, coronavirus disease 2019; IBD, inflammatory bowel disease; ICU, intensive care unit.
In one study of 2246 unvaccinated patients who were at high risk for progression to severe disease, those receiving Paxlovid within 5 days of symptom onset had an 89% reduction in progression to severe COVID infection.\(^2\) In a recent database study, Paxlovid on treatment had an 89% reduction in progression to severe disease for those receiving Paxlovid within 5 days of symptom onset.\(^2\) Those receiving Paxlovid within 5 days of symptom onset had an 89% reduction in progression to severe disease,\(^2\) indicating no decreased efficacy of Paxlovid in IBD patients when compared with propensity-matched non-IBD controls. In the small cohort of patients who received Lagevrio, we did not see any reduction in hospitalization. We encourage clinicians to consider use of Paxlovid in high-risk patients with IBD who develop COVID-19 infection as described by the National Institutes of Health.\(^6\)

### Table 1. Outcomes of COVID-19 in IBD Patients in the Paxlovid and Lagevrio Cohorts Compared With the IBD Control Cohort After Propensity-Score Matching

| Outcome                  | Cohort          | N (%) | aOR   | 95% CI |
|--------------------------|-----------------|-------|-------|--------|
| Hospitalization          | Paxlovid        | 10 (1.8)\(^a\) | 0.35  | 0.17–0.74 |
|                          | No antiviral    | 27 (6.0)  |       |        |
| Intubation/respiratory support | Paxlovid    | 0 (0)  | N/A   | N/A    |
|                          | No antiviral    | 10 (1.8)\(^a\) |       |        |
| Mortality                | Paxlovid        | 0 (0)  | N/A   | N/A    |
|                          | No antiviral    | 10 (1.8)\(^a\) |       |        |
| ICU care                 | Paxlovid        | 0 (0)  | N/A   | N/A    |
|                          | No antiviral    | 10 (1.8)\(^a\) |       |        |
| Hospitalization          | Lagevrio        | 10 (6.7)\(^a\) | 0.75  | 0.31–1.77 |
|                          | No antiviral    | 13 (8.7)  |       |        |
| ICU care                 | Lagevrio        | 0 (0)  | N/A   | N/A    |
|                          | No antiviral    | 10 (6.7)\(^a\) |       |        |
| Intubation/respiratory support | Lagevrio  | 0 (0)  | N/A   | N/A    |
|                          | No antiviral    | 10 (6.7)\(^a\) |       |        |

\(^a\)To maintain patient confidentiality, when numbers of events are >1 but <10, TrinNetX rounds up events to 10.

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Conflicts of interest
These authors disclose the following: Francis A. Farraye is a consultant for BMS, Braintree Labs, GSK, IBD Educational Group, Innovation Pharmaceuticals, Janssen, Pfizer, and Sebela; and is a member of the Data and Safety Monitoring Board for Adiso Therapeutics and Lilly. The remaining authors disclose no conflicts.
### Supplementary Table 1. Comparison of Demographic Parameters, IBD Types, Comorbid Diseases, and IBD Medications Between Patients in the Paxlovid and Control Cohorts Before and After Propensity-Score Matching

| Demographics | Paxlovid cohort (n = 532) | Control cohort (n = 29,589) | P value | Paxlovid cohort (n = 531) | Control cohort (n = 531) | P value |
|--------------|---------------------------|----------------------------|---------|---------------------------|----------------------------|---------|
| Age, y, mean ± SD | 55.2 ± 16.2 | 50.3 ± 19.5 | <.0001 | 55.2 ± 16.2 | 56.2 ± 17.1 | .34 |
| BMI, means ± SD | 30.5 ± 6.5 | 29.1 ± 7.2 | .01 | 30.5 ± 6.5 | 29.6 ± 6.8 | .95 |
| Female gender | 331 (62%) | 17811 (60%) | .32 | 330 (62%) | 339 (63%) | .56 |
| Hispanic or Latino | 11 (2%) | 1391 (4.7%) | .004 | 11 (2%) | 14 (2.6%) | .54 |
| Race | | | | | | |
| White | 477 (89%) | 23825 (80%) | <.0001 | 476 (89%) | 467 (87%) | .38 |
| African American | 28 (5.2%) | 3437 (11%) | <.0001 | 28 (5.2%) | 33 (6.2%) | .50 |
| COVID vaccine | | | | | | |
| BNT162b2 (Pfizer) | 80 (15%) | 1074 (3.6%) | <.0001 | 79 (14%) | 71 (13%) | .48 |
| Messenger RNA-1273 (Moderna) | 16 (3%) | 226 (0.7%) | <.0001 | 16 (3%) | 20 (3.7%) | .49 |
| Ad26.COV2.S (Johnson & Johnson) | 10 (1.8%) | 18 (0.6%) | <.0001 | 10 (1.8%) | 10 (1.8%) | 1 |
| IBD type and subtype | | | | | | |
| UC | 319 (59%) | 13873 (46%) | <.0001 | 318 (59%) | 331 (62%) | .41 |
| Ulcerative proctitis | 52 (9.7%) | 2134 (7.2%) | .02 | 51 (9.6%) | 50 (9.4%) | .91 |
| Ulcerative rectosigmoiditis | 47 (8.8%) | 1491 (5%) | <.0001 | 46 (8.6%) | 45 (8.4%) | .91 |
| Left-sided colitis | 24 (4.5%) | 1381 (4.6%) | .86 | 24 (4.5%) | 21 (3.9%) | .64 |
| UC pancolitis | 110 (20%) | 4458 (15%) | .003 | 109 (21%) | 107 (20%) | .87 |
| CD | 297 (55%) | 14318 (48%) | .007 | 296 (55%) | 287 (54%) | .57 |
| CD of small intestine | 132 (24%) | 5648 (19%) | .009 | 132 (24%) | 126 (23%) | .66 |
| Bowel obstruction/stricture | 25 (4.6%) | 855 (2.8%) | .01 | 25 (4.7%) | 21 (3.9%) | .54 |
| Fistula | 19 (3.5%) | 441 (1.4%) | .001 | 19 (3.5%) | 25 (4.7%) | .35 |
| Abscess | 10 (1.8%) | 186 (0.6%) | .004 | 10 (1.8%) | 10 (1.8%) | 1 |
| CD of large intestine | 164 (30%) | 5752 (19%) | <.0001 | 163 (30%) | 158 (29%) | .73 |
| Intestinal | 13 (2.4%) | 367 (1.2%) | .01 | 13 (2.4%) | 10 (1.8%) | .52 |
| Bowel obstruction/stricture | 22 (4.1%) | 665 (2.2%) | .003 | 22 (4.1%) | 21 (3.9%) | .87 |
| Fistula | 11 (2%) | 312 (1%) | .02 | 11 (2%) | 14 (2.6%) | .54 |
| Abscess | 130 (24%) | 4404 (14%) | <.0001 | 130 (24%) | 118 (22%) | .38 |
| CD of small and large intestine | 25 (4.6%) | 726 (2.4%) | .001 | 25 (4.7%) | 19 (359%) | .35 |
| Fistula | 11 (2%) | 279 (0.9%) | .008 | 11 (2%) | 12 (2.2%) | .83 |
| Abscess | 10 (1.8%) | 342 (1.1%) | .12 | 10 (1.8%) | 10 (1.8%) | 1 |
| Total colectomy | 10 (1.8%) | 86 (0.2%) | <.0001 | 10 (1.8%) | 10 (1.8%) | 1 |
| Comorbid diseases | | | | | | |
| Diabetes mellitus | 113 (21%) | 7833 (26%) | .006 | 113 (21%) | 116 (21%) | .82 |
| Nicotine dependence | 92 (17%) | 6151 (20%) | .04 | 91 (17%) | 81 (15%) | .40 |
| Ischemic heart disease | 91 (17%) | 6560 (22%) | .005 | 91 (17%) | 90 (16%) | .93 |
| Chronic lower respiratory disease | 230 (43%) | 12122 (40%) | .28 | 230 (43%) | 221 (41%) | .57 |
| Chronic kidney disease | 81 (15%) | 6841 (23%) | <.0001 | 81 (15%) | 81 (15%) | 1 |
| Heart failure | 42 (7.8%) | 3990 (13%) | .002 | 42 (7.9%) | 47 (8.8%) | .57 |
| Medications | | | | | | |
| Prednisone | 97 (18%) | 5411 (18%) | .97 | 97 (18%) | 88 (16%) | .46 |
| Budesonide | 35 (6.5%) | 2268 (7.6%) | .35 | 35 (6.5%) | 31 (5.8%) | .61 |
| Methylprednisolone | 79 (14%) | 3591 (12%) | .05 | 78 (14%) | 69 (12%) | .42 |
| Infliximab | 78 (14%) | 3396 (11%) | .02 | 78 (14%) | 68 (12%) | .37 |
| Demographics       | Before propensity-score matching | After propensity-score matching | P value | P value |
|-------------------|----------------------------------|---------------------------------|---------|---------|
|                   | Paxlovid cohort (n = 532)        | Control cohort (n = 29,589)     |         |         |
| Adalimumab        | 92 (17%)                         | 3736 (11%)                      | .001    | .35     |
| Golimumab         | 10 (1.8%)                        | 175 (0.5%)                      | .0002   | 1       |
| Certolizumab      | 10 (1.8%)                        | 405 (1.3%)                      | .31     | 1       |
| Vedolizumab       | 42 (7.8%)                        | 1522 (5%)                       | .004    | .55     |
| Ustekinumab       | 50 (9.3%)                        | 1375 (4.6%)                     | <.0001  | .66     |
| Tofacitinib       | 10 (1.8%)                        | 329 (1.1%)                      | .09     | 1       |
| Azathioprine      | 62 (11%)                         | 3132 (10%)                      | .42     | .03     |
| Methotrexate      | 41 (7.7%)                        | 2120 (7.1%)                     | .62     | .73     |
| Mercaptopurine    | 32 (6%)                          | 1437 (4.8%)                     | .21     | .89     |

NOTE. One-to-one (1:1) propensity-score matching was performed for age, gender, race, ethnicity, obesity, diabetes mellitus, tobacco abuse, chronic lower respiratory disease, ischemic heart disease, heart failure, chronic kidney disease, steroids, IBD medications, and COVID-19 vaccine. After propensity-score matching, the risk of each outcome was expressed as an adjusted odds ratio with 95% CI. Baseline demographic characteristics, laboratory parameters, and medication use within 3 months of initiation of COVID-19 antiviral therapies were described using means, SDs, and proportions. Two-sided P values less than .05 were considered statistically significant. To maintain patient confidentiality, when numbers of events are greater than 1 but fewer than 10, TriNetX rounds up events to 10.

BMI, body mass index; CD, Crohn’s disease; COVID-19, coronavirus disease 2019; IBD, inflammatory bowel disease; N/A, not applicable; UC, ulcerative colitis.

*Total UC and CD is not 100% owing to possible overlap of International Classification of Diseases, 10th revision, Clinical Modification codes in patients

*Medications prescribed within 6 months before prescription of Paxlovid.
### Supplementary Table 2. Comparison of Demographic Parameters, IBD Types, Comorbid Diseases, and IBD Medications Between Patients in the Lagevrio and Control Cohorts Before and After Propensity-Score Matching

| Demographics          | Before propensity-score matching | After propensity-score matching |
|-----------------------|----------------------------------|---------------------------------|
|                       | Lagevrio cohort (n = 150)        | Control cohort (n = 29,589)     | Lagevrio cohort (n = 149) | Control cohort (n = 149) |
|                       | Age, y                           | 59.7 ± 16.5                    | 50.3 ± 19.5              | 59.6 ± 16.5              | 59 ± 16.8              | .75                      |
|                       | BMI                              | 29.9 ± 6.09                    | 29.1 ± 7.26              | 29.9 ± 6.11              | 30.2 ± 6.69              | .78                      |
|                       | Female gender                    | 100 (66%)                      | 17811 (60%)              | 99 (66%)                 | 101 (67%)               | .80                      |
|                       | Hispanic or Latino               | 10 (6.6%)                      | 1391 (4.7%)              | 10 (6.7%)                | 10 (6.7%)               | 1                        |
|                       | Race                             | White 139 (92%)                | 23825 (80%)              | 138 (92%)                | 134 (89%)               | .41                      |
|                       |                                  | African American 10 (6.7%)    | 3437 (11%)               | 10 (6.7%)                | 11 (7.3%)               | .82                      |
|                       |                                  |                                |                          |                          |                          |                          |
|                       | COVID vaccine                    |                                |                          |                          |                          |                          |
|                       |                                  | BNT162b2 (Pfizer) 10 (6.7%)    | 1074 (3.6%)              | 10 (6.7%)                | 13 (8.7%)               | .51                      |
|                       |                                  | Messenger RNA-1273 (Moderna)   | 10 (6.7%)                | 10 (6.7%)                | 10 (6.7%)               | 1                        |
|                       |                                  | Ad26.COV2.S (Johnson & Johnson)| 10 (6.7%)                | 18 (0.06%)               | <.0001                  |                         |
|                       | IBD type and subtype             |                                |                          |                          |                          |                          |
|                       |                                  | UC 84 (56%)                    | 13873 (46%)              | 83 (55%)                 | 71 (47%)                | .16                      |
|                       |                                  | Ulcerative proctitis 15 (10%) | 2134 (7.2%)              | 15 (10%)                 | 15 (10%)                | 1                        |
|                       |                                  | Ulcerative rectosigmoiditis    | 10 (6.7%)                | 1491 (5%)                | 10 (6.7%)               | 10 (6.7%)               | 1                        |
|                       |                                  | Left-sided colitis 10 (6.7%)  | 1381 (4.6%)              | 10 (6.7%)                | 10 (6.7%)               | 10 (6.7%)               | 1                        |
|                       |                                  | UC pancolitis 32 (21%)         | 4458 (15%)               | 32 (21%)                 | 32 (21%)                | 22 (14%)                | .13                      |
|                       | UC                              | CD 82 (54%)                    | 14318 (48%)              | 52 (34%)                 | 43 (28%)                | .26                      |
|                       |                                  | CD of small intestine 30 (20%) | 5648 (19%)               | 30 (20%)                 | 34 (22%)                | .57                      |
|                       |                                  | Intestinal 10 (6.7%)          | 855 (2.8%)               | 10 (6.7%)                | 10 (6.7%)               | 1                        |
|                       | Fistula                          | 441 (1.4%)                    | <.0001                   | 10 (6.7%)                | 10 (6.7%)               | 1                        |
|                       | Abscess                          | 186 (0.6%)                    | .33                      | 0                       | 0                       | N/A                      |
|                       | CD of large intestine 30 (20%)   | 5742 (19%)                    | .85                      | 30 (20%)                 | 22 (14%)                | .87                      |
|                       | Intestinal obstruction/stricture  | 367 (1.2%)                    | <.001                    | 10 (6.7%)                | 0                       | .0013                    |
|                       | Fistula                          | 665 (2.2%)                    | .0003                    | 10 (6.7%)                | 0                       | 0                       | N/A                      |
|                       | Abscess                          | 312 (1%)                      | .20                      | 0                       | 0                       | N/A                      |
|                       | CD of small and large intestine  | 4404 (14%)                    | .76                      | 21 (14%)                 | 31 (20%)                | .1                       |
|                       | Fistula                          | 726 (2.4%)                    | .05                      | 0                       | 0                       | N/A                      |
|                       | Abscess                          | 279 (0.9%)                    | .23                      | 0                       | 0                       | N/A                      |
|                       | Small intestine resection        | 10 (0.03%)                    | .82                      | 0                       | 0                       | N/A                      |
|                       | Total colectomy                  | 86 (0.2%)                     | <.0001                   | 10 (6.7%)                | 10 (6.7%)               | 1                        |

| Comorbid diseases     | Before propensity-score matching | After propensity-score matching |
|-----------------------|----------------------------------|---------------------------------|
| Diarrhea mellitus     | 52 (34%)                        | 7833 (26%)                      | 52 (34%)                 | 43 (28%)                 | .26                      |
| Nicotine dependence   | 22 (14%)                        | 6151 (20%)                      | 22 (14%)                 | 20 (13%)                 | .73                      |
| Ischemic heart disease| 43 (28%)                        | 6560 (22%)                      | 43 (28%)                 | 39 (26%)                 | .60                      |
| Chronic lower         | 87 (58%)                        | 12122 (40%)                     | <.0001                   | 86 (57%)                 | 86 (57%)                 | 1                        |
| Respiratory disease   |                                 |                                |                          |                          |                          |                          |
| Chronic kidney disease| 51 (34%)                        | 6841 (23%)                      | .001                     | 51 (34%)                 | 47 (31%)                 | .62                      |
| Heart failure         | 23 (15%)                        | 3990 (13%)                      | .50                      | 23 (15%)                 | 22 (14%)                 | .87                      |

| Medications           | Before propensity-score matching | After propensity-score matching |
|-----------------------|----------------------------------|---------------------------------|
| Prednisone            | 22 (14%)                         | 5411 (18%)                      | 22 (14%)                 | 21 (14%)                 | .86                      |
| Budesonide            | 10 (6.6%)                        | 2268 (7.6)                      | 10 (6.6%)                | 10 (6.6%)                | 1                        |
| Methyprednisolone     | 12 (8%)                          | 3591 (12%)                      | 12 (8%)                  | 10 (6.6%)                | .65                      |
| Infliximab            | 15 (10%)                         | 3396 (11%)                      | 15 (10%)                 | 15 (10%)                 | 1                        |
| Adalimumab            | 21 (14%)                         | 3736 (12%)                      | 21 (14%)                 | 23 (15%)                 | .74                      |
| Golimumab             | 10 (6.6%)                        | 175 (0.5%)                      | <.0001                   | 10 (6.6%)                | 10 (6.6%)               | 1                        |
| Certolizumab          | 10 (6.6%)                        | 405 (1.3%)                      | <.0001                   | 10 (6.6%)                | 10 (6.6%)               | 1                        |
| Vedolizumab           | 10 (6.6%)                        | 1522 (5.1%)                     | .39                      | 10 (6.6%)                | 10 (6.6%)               | 1                        |
### Supplementary Table 2. Continued

| Demographics       | Before propensity-score matching | After propensity-score matching |
|--------------------|----------------------------------|---------------------------------|
|                    | Lagevrio cohort (n = 150)         | Control cohort (n = 29,589)     | P value | Lagevrio cohort (n = 149) | Control cohort (n = 149) | P value |
| Ustekinumab        | 10 (6.6%)                        | 1375 (4.6%)                    | .24     | 10 (6.6%)                  | 10 (6.6%)                  | 1.0     |
| Tofacitinib        | 10 (6.6%)                        | 329 (1.1%)                     | <.0001  | 10 (6.6%)                  | 10 (6.6%)                  | 1.0     |
| Azathioprine       | 20 (13%)                         | 3132 (10%)                     | .27     | 20 (13%)                   | 22 (14%)                   | 1.0     |
| Methotrexate       | 12 (8%)                          | 2120 (7%)                      | .69     | 12 (8%)                    | 17 (11%)                   | .32     |
| Mercaptopurine     | 10 (6.6%)                        | 1437 (4.8%)                    | .30     | 10 (6.6%)                  | 10 (6.6%)                  | 1.0     |

**NOTE.** To maintain patient confidentiality, when numbers of events are greater than 1 but fewer than 10, TriNetX rounds up events to 10.

BMI, body mass index; CD, Crohn’s disease; COVID, coronavirus disease; IBD, inflammatory bowel disease; N/A, not applicable; UC, ulcerative colitis.

*Total UC and CD is not 100% owing to possible overlap of International Classification of Diseases, 10th revision, Clinical Modification codes in patients.*

*bMedications prescribed within 6 months before prescription of Lagevrio.*